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S C Supreme Court

THE STATE OF SOUTH CAROLINA

In the Supreme Court

APPEAL FROM RICHLAND COUNTY
In The Court of Common Pleas

James R Barber, III, Circuit Court Judge
G Thomas Copper, Jr , Circuit Court Judge

Opinion No 4592 (S C Ct App Filed July 15, 2009)

Monica Weston — Petitioner,

v

Kims Dollar Store and
CIBA Vision, a division of Novartis Company — Respondents

BRIEF OF RESPONDENT CIBA VISION

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STATEMENT OF QUESTIONS PRESENTED BY PETITIONER

This matter comes to the Court through Appellant's Petition for Writ of Certiorari The issues presented in the Petition were four-fold

1 CIBA is entitled to preemption if and only if it received a pre-market approval (PMA) letter for its non-corrective lenses

2 Viewing the evidence, inferences, and ambiguities in the light most favorable to Petition, and construing the same most strongly against CIBA, there is a question of fact as to whether CIBA applied for and/or received PMA approval for its non-corrective lenses

3 The Court of Appeals misapprehended how MDA preemption comes into existence and therefore misapprehended the requisite showing for summary judgment on the issue of preemption

4 The Court of Appeals misapprehended Customer's jurisdiction argument and appeared to usurp the exclusive jurisdiction of the FDA

STATEMENT OF THE CASE

In the recent case *Riegel v Medtronic, Inc* the United States Supreme Court clarified how the (express preemption provision) in the federal Medical Device Amendments' ("MDA") should be applied to devices regulated as Class III medical devices by the Food & Drug Administration (FDA) 552 U S 312 999 (2008) *Riegel* is the current seminal case on medical device preemption *Lundeen v Canadian Pacific R Co* , 532 F 3d 682, 698 (8th Cir 2008) ("*Riegel* is [now] the primer from which we read") The present petition represents the first opportunity for the South Carolina Supreme Court to address medical device preemption after *Riegel* (*See infra* for a list of numerous other states and jurisdiction which have affirmed summary judgment of medical device claims following *Riegel*) *Riegel* virtually mandates preemption in this

case and substantially modified the holdings of *Medtronic Inc v Lohr* 518 U S 470 (1996), on which Petitioner relies in her brief (Pet 's Br p 8) [1]

The claims in *Riegel* arose after plaintiff's surgeon overinflated a Medtronic catheter while performing a coronary angioplasty, causing the catheter to rupture On review, the United States Supreme Court affirmed dismissal of plaintiff's strict liability, breach of implied warranty, and negligent design, testing, inspection, distribution, labeling, marketing, and sale claims on the grounds that they were expressly preempted by the MDA *Riegel*, 552 U S at 320-322

In *Riegel*, after recounting its prior preemption cases, the Court established a two-prong test for determining if a state-law tort claim is preempted by 21 U S C § 360k The first prong determines the FDA requirements applicable to the device at issue, and the second prong determines whether the state law or civil action at issue creates a requirement that is "different from or in addition to the federal requirement " 552 U S at 322-323

Petitioner Monica Weston ("Weston") alleges causes of action for personal injury against Respondent CIBA Vision, a Novartis Company ("CIBA"), stemming from her alleged illegal use of contact lenses purchased by her without a prescription from Respondent Kim's Dollar Store (Amend Compl paras [8, 12, 15, 19, 24]) (R pp 38-40) Weston's petition arises from partial summary judgment of certain causes of action

[1] Post-*Riegel*, federal courts have found "reliance upon the highly fractured opinion of the Supreme Court in the pre- *Riegel* case of *Medtronic Inc v Lohr* 518 U S 470 (1996) is misplaced " *Dorsey v Allergan Inc* No 3 08-0731 2009 WL 703290, *6 (M D Tenn Mar 11, 2009) (noting that *Riegel* limited *Lohr* to "generic concerns about device regulation generally")

that were dependent on warning, labeling, design, marketing and/or misbranding theories, as those claims were preempted by federal law (Order Granting SJ, R p 17) Weston's claims for negligence per se, strict liability and breach of implied warranty were not dismissed and remain pending in the trial court If Weston prevails on the remaining causes of action, she likely will be forced to make an election of remedies Thus, in essence, Weston brings this petition, merely to preserve her options

In June 2006, Respondent CIBA filed a motion for partial summary judgment on the basis that certain of Petitioner Weston's claims and legal theories were subject to federal preemption pursuant to the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (21 U S C § 301, *et seq*) (FDCA)) The Honorable G Thomas Cooper, Jr , held an extended hearing on CIBA's motion for summary judgment on August 28, 2006 On November 28, 2006, Judge Cooper issued an 18-page order granting summary judgment in favor of CIBA on the issue of federal preemption (the "Order"), thereby terminating certain of Weston's multiple claims and theories (R pp 1-18) Following the denial of Weston's motion for reconsideration, Weston filed an appeal on January 19, 2007 The South Carolina Court of Appeals affirmed the dismissal of certain claims and theories in its lengthy opinion of July 15, 2009 Following the denial of a motion for reconsideration and a post-argument motion to supplement the record on appeal, Weston filed this petition

The focus of Petitioner's opposition to summary judgment and her appeal to the South Carolina Court of Appeals was "whether FreshLook Colors lenses were a medical device" (Final Brief of Appellant before the Court of Appeals, p 1) However, in her brief before this Court, Petitioner now concedes that these "[c]ontact lenses are a Class

III Medical Device under the MDA" (Petitioner Statement of the Case, p 4) Consequently, review of the briefs filed below and much of the Record on Appeal relates to matters no longer contested by Petitioner Instead, the issues now focused on by Petitioner all pertain to whether the particular Class III medical device at issue received PMA approval

STATEMENT OF FACTS

It is Petitioner Weston's contention that she suffered temporary loss of vision in one eye as a result of wearing non-corrective color contact lenses manufactured by CIBA under the trade name, FreshLook Colors ("FreshLook") (Amend Compl ¶¶ 3, 18-24, of Hearing ("Transcript") pp 4, 7)) (R pp 37, 39-40, 264, 267) The individual contact lenses Weston allegedly purchased from Kim's Dollar Store were marked "prescription only" and labeled "not to be sold individually" (Oris Dep pp 59-60, Ex 4) (R pp 470-471, 588) Notwithstanding this sales restriction, Kim's Dollar Store, an unauthorized and unlicensed seller of contact lenses, obtained the lenses from an unknown third party (30(b)(6) Dep of Kim's Dollar Store pp 37-38, Pl 's Exhibit 1) (R pp 316-317, 322) Weston discarded the lenses rendering them unavailable to confirm the brand, manufacturer or other physical information

FreshLook contact lenses came in a variety of colors and a range of powers from (-)20 00 Diopters to (+)20 00 Diopters They are also capable of correcting nearsightedness, farsightedness, and astigmatism At the zero-power point in the range, the lenses are "non-corrective" or "plano" lenses, although they still have medical and physiological effects, including protection from damaging UV radiation In addition, plano contact lenses can be used to change the color of the user's eye and to address

medical issues, such as monovision and ocular defects (Parisian Dep p 144) (R p 654) [2]

In framing the issue underlying this petition, Weston asserts that federal preemption arises only if FreshLook plano contact lenses were approved by the FDA as "medical devices" under its premarket approval (PMA) process This issue, however, was exactly the one decided in CIBA's favor on summary judgment as set forth in detail in Judge Cooper's Order (R p 1-18) and affirmed by the Court of Appeals Weston then immediately ignores the issue she frames and, in *ad hominem* fashion, attacks CIBA for its advertising campaigns, eye catching graphics, and awareness of possible unauthorized product resales [3] These points are irrelevant because Petitioner now concedes that these "[c]ontact lenses are a Class III Medical Device under the MDA " (Pet 's Br Statement of the Case p 4) Moreover, designation as a Class III Medical Device establishes that the FDA was actively regulating all versions and uses of FreshLook contact lenses through its medical device PMA authority The FDA has <u>not</u> carved out one version of FreshLook lenses for different treatment For this Court to do, so as Petitioner requests, would require concluding that the FDA purposefully failed to regulate this admittedly Class III Medical Device As deomonstrated below, this conclusion is incorrect, unreasonable and irresponsible

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[2] Dr Suzanne Parisian was Petitioner Weston's expert on the issue of federal preemption

[3] That a device manufacturer advertises one use at one time through a particular medium has no effect on the device's regulatory status For example, human-based collagen injection products are PMA-approved by the FDA for improvements of soft tissue appearance "such as wrinkles and acne scars "
(http //www fda gov/cdrh/pdf3/p800022s050a pdf) That the manufacturer chooses to educate the "wrinkle" audience with TV commercials, while educating the "acne scar" audience with product information at the dermatologist's office, does not render collagen injections something less than regulatory classification

LEGAL FRAMEWORK

The question of federal preemption under the Medical Devices Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act (FDCA) is a preliminary question of law for the court to decide *Cox v Shalala*, 112 F 3d 151 (4th Cir 1997) This legal question is specifically "reserved to the Court and is properly resolved on summary judgment" *Clark v Medtronic Inc* , 572 F Supp 2d 1090, 1093 (D Minn 2008) (finding preemption under the MDA and granting summary judgment)

If the Court finds federal preemption applicable, then there cannot be a genuine issue of material fact as to the preempted state law claims *Anderson v Liberty Lobby Inc* , 477 U S 242, 248 (1986) ("only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment ") (emphasis added), *Gomez v St Jude Medical Daig Div Inc* , 442 F 3d 919, 933 (5th Cir 2006) (holding summary judgment was appropriate where "claims cannot be presented to a jury because, if successful, they would be inconsistent with the federal regulatory requirements"), *Crain v Board of Police Comm'rs of Metro Police Dep't* , 920 F 2d 1402, 1405-06 (8th Cir 1990) (when "unresolved issues are primarily legal rather than factual, summary judgment is particularly appropriate"), *Scanga v Johnson & Johnson Inc* , 1995 WL 17147946, *2 (W D Pa September 14, 1995) (noting that "preemption - is a question of law particularly suited for summary judgment"), *Leonardis v Burns Intern Sec Services Inc* , 808 F Supp 1165, 1172 (D N J 1992) (when preemption exists it is appropriate to grant summary judgment)

Granting summary judgment on the legal question of preemption is appropriate even when the court must weigh factual considerations in fulfilling its obligation to

determine the question of law *Sloan v Greenville Hosp System*, 388 S C 152, 155-56, 694 S E 2d 532, 534 (2010) (finding factual dispute between the parties as to whether Greenville Hospital System was a "governmental body" or "political subdivision" did not preclude summary judgment of related "question of law")[4] Merely posing a factual disagreement is not enough to defeat summary judgment, especially when those findings relate to matters reserved for determination by the court rather than by the jury *Zabinski v Bright Acres Associates*, 346 S C 580, 594, 553 S E 2d 110, 117 (2001) (holding that in determining legal issue of whether parties engaged in interstate commerce, "the court must examine the agreement, the complaint, and the surrounding facts"), *Thornton v Trident Medical Center LLC*, 357 S C 91, 94, 592 S E 2d 50, 51 (Ct App 2003) (holding that on the legal question of arbitrability, "a circuit court's factual findings will not be reversed on appeal if there is any evidence reasonably supporting the findings")

Similarly, if the Court encounters an inferential divide in resolving the question of law, it is not thrown into legal purgatory as Petitioner suggests Rather, the Court must draw its own inference in order to answer the question of law *See e g S C Energy Users Committee v S C Pub Ser Comm'n*, 388 S C 486, 491, 697 S E 2d 587, 590 (2010) ("[I]f the statute is ambiguous, however, courts must construe the terms of the statute ") (emphasis added) Once the Court construes a statute, regulation or agency requirement, any ambiguity evaporates This is the essence of the general summary judgment standard There can be only one reasonable interpretation as to a question of law the on

[4] Petitioner's reference to the standard in the *Tupper v Dorchester* case is misleading, as it expressly addresses summary judgment involving a "question of fact not a question of law " 326 S C 318, 323, 487 S E 2d 187, 190 (1997) ("The existence of an easement is a question of fact ")

interpretation of the court *Brooks v Northwood Little League Inc*, 327 S C 400, 403, 489 S E 2d 647, 648 (Ct App 1997) (finding whether T-ball fell within scope of the state statute related to "summer sports" was for the Court on summary judgment), *Byrd v Irmo High School*, 321 S C 426, 440, 468 S E 2d 861, 869 (1996) (holding further factual development would not aid in resolution of interpretation of disputed legal question)

Even if preemption were a question of fact for the jury to decide, CIBA would be entitled to summary judgment Petitioner concedes that these "lenses are Class III Medical Devices under the MDA" (Pet 's Br p 4) CIBA introduced persuasive and compelling evidence, as reflected in the Record on Appeal, which establishes beyond contradiction that the contact lenses allegedly worn by Petitioner were regulated as approved Class III Medical Devices by the FDA and subject to preemption Meeting this evidence with a mantra of "that's not good enough" is not sufficient to prevent summary judgment In the face of such evidence, Petitioner is required to put forth substantive countervailing evidence Under the governing law of the MDA, partial summary judgment was appropriate because there is no factual scenario in which Petitioner could prevail on the preempted state law claims

FEDERAL PREEMPTION UNDER THE MDA

The principle of preemption arises from the Supremacy Clause of the United States Constitution, which states "the Laws of the United States shall be the supreme Law of the Land, and the Judges in every State shall be bound thereby, any thing in the Constitution or Laws of any State to the Contrary notwithstanding" *City of Cayce v Norfolk Southern Ry Co*, 391 S C 395, 400, 706 S E 2d 6, 8 (2011) (citing U S Const

art VI, cl 2) Federal preemption of state law causes of action is principally a matter of congressional intent, with the purpose of Congress being the "ultimate touchstone ' *Pilot Life Ins Co v Dedeaux*, 481 U S 41, 45-46 (1987) When preemption is made expressly a part of the congressional act, "the preemption inquiry must focus on the plain wording of that provision, which generally contains the most reliable evidence as to whether Congress intended to preempt state law " *City of Cayce* 391 S C at 402 S E 2d In conducting this analysis, a court must be guided by "the provisions of the whole law, and its object and policy " *Pilot Life Ins* 481 U S at 51 With regard to the MDA, the United States Supreme Court recently noted that Congress was driven by concern "for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations " *Riegel*, 522 U S at 326 In granting summary judgment in a post-*Riegel* case involving the scope of FDA premarket approval, the United States District Court for the Northern District of Ohio succinctly noted that "Congress has constructed the statutory scheme, and the Supreme Court has interpreted it as pre-empting the complaint Plaintiffs have filed in this matter " *Wilhite v Howmedica Osteonics Corp* , 2011 WL 2530984 (N D Ohio 2011) [5]

With the passage of the MDA, 20 U S C § 301, *et seq* , Congress "swept back some state obligations and imposed a regime of detailed federal oversight " *Riegel* 552

[5] In viewing the whole law and the objects and policies related to the federal oversight of medical devices by the FDA, the intent is very similar to federal preemption applicable to the railroad industry Regarding railroad preemption, this Court recently noted that the purpose is "to prevent the development of a patchwork of local and state regulations affecting the railroad industry, as the enactment of differing standards and requirements would inevitably be detrimental to the orderly functioning of the industry as a whole " *City of Cayce v Norfolk Southern,* 391 S C at 407

U S 316 The MDA included an "express"[6] pre-emption provision which supersedes any state action that is "different from, or in addition to, any requirement applicable under this chapter to the device and which relates to any matter included in a requirement applicable to the device under this chapter " 21 U S C § 360k(a), *Riegel*, 552 U S at 316

In *Riegel*, the United States Supreme Court also clarified how this preemption provision is to be applied First, a court must determine whether the FDA has imposed safety-related requirements on the device in question 552 U S at 322–323 On this issue, the *Riegel* Court held that the PMA approval process imposes federal "requirements" upon the subject medical devices because "the FDA may grant premarket approval only after it determines that a device offers reasonable assurance of safety and effectiveness " *Id* at 323 Accordingly, for all PMA-approved devices, this first prong is met *Lewkut v Stryker Corp* , 724 F Supp 2d 648, 654 (S D Tex 2010) Second, the *Riegel* Court held that a court must determine whether the state law claims for relief brought by a plaintiff impose requirements that are "different from, or in addition to" the FDA's requirements 552 U S at 323 On this issue the *Riegel* Court concluded that state tort claims for negligence and strict liability impose requirements additional to the requirements imposed through the PMA process *Id* at 323–327 *see also Lewkut*, 724 F Supp 2d at 653-654 In applying preemption, Petitioner asserts that the courts are guided by a strict presumption against preemption This preemption is not applicable to MDA

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[6] Petitioner incorrectly suggests that this case involves "conflict" preemption (Petitioners Brief p 10) However the Court in *Riegel* held that preemption under the MDA is express preemption *See also McMullen v Medtronic Inc* , 421 F 3d 482, 486-487 (7th Cir 2005) ("The MDA contains an express preemption provision, [a]ccordingly, we do not address the doctrines of conflict and field preemption")

preemption as set forth in the framework established by *Riegel* In R*iegel*, the Second Circuit in *Riegel* recognized the general presumption against preemption, but found it inapplicable to blocking preemption under the MDA with regard to state court tort actions affecting Class III medical devices *Riegel v Medtronic Inc* , 451 F 3d 104, 123 (2d Cir 2006), arr'm 552 U S 312, 128 S Ct 99 (2008)

Petition concedes that these contact lenses are Class III Medical Devices (Pet 's Br p 4) A Class III Medical Device may only be marketed pursuant to the FDA's PMA process (subject to certain limited exceptions not relevant here) *See* FDCA § 515, 21 U S C § 360e As the Seventh Circuit explained in a case similarly finding federal preemption of product liability claims

> Before a Class III device may be introduced to the market, the manufacturer must provide the [FDA] with a reasonable assurance that the device is safe and effective under the MDA To provide that assurance, a manufacturer must obtain premarket approval ("PMA") from the FDA This procedure is a "rigorous" process, in which the manufacturer must submit detailed information to the FDA regarding the safety and effectiveness of the device Manufacturers must provide the FDA with samples of the device, an outline of the device's components and properties, a description of the manufacturing process, copies of the proposed labels, various other data and information, and any other information the FDA requests The FDA spends an average of 1,200 hours per PMA application reviewing these materials

Mitchell v Collagen Corp , 126 F 3d 902, 905 (7th Cir 1997), *cert denied*, 523 U S 1020 (1998) In addition, FDA regulations permit manufacturers to seek approval for device modifications by submitting supplements to a prior PMA "All procedures and actions that apply to [a PMA] application also apply to PMA supplements " 21 C F R § 814 39 The PMA supplement process obviates the need to submit redundant

information to the FDA regarding design features, manufacturing processes, or labeling that has already been approved by the FDA At the same time, the entirety of the PMA, including all supplements are, "before' the agency at the time the supplement is reviewed " 51 Fed Reg 26342, 26354 (1986) The "FDA considers revisions proposed in a PMA supplement using the same type of rigorous scientific process utilized for review of original PMAs " *See* FDA Letter Brief filed as *amicus curiae*, *Horn v Thoratec*, 376 F 3d 163 (3d Cir 2004), available at 2004 WL 1143720, at *10 (May 14, 2004) (Amicus Brief"), *see also Riegel*, 552 U S at 319 ("An application for supplemental premarket approval [is] evaluated under largely the same criteria as an initial application § 360e(d)(6)") [7] Consequently, every approval of a PMA supplement application is a renewal of the original PMA approval and the prior related PMA supplements [8]

PMA approval of a medical device by the FDA results in device-specific federal requirements that preempt inconsistent state requirements, including those sought to be imposed through tort liability *Riegel*, 552 U S at 320-323, *Horn v Thoratec Corp* , 376 F 3d 163 (3d Cir 2004), *Martin v Medtronic Inc* , 254 F 3d 573 (5th Cir 2001), *Kemp* 231 F 3d 216 Specifically, the MDA expressly preempts any state law requirement "(1)

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[7] Petitioner, without citing any authority, baldly asserts that the PMA supplement process is an "add-on" system that cannot be considered "evidence" sufficient to support preemption (Pet 's Br , p 13) This is directly contrary to the law, Congress's intent in enacting the MDA, United States Supreme Court precedent and the FDA oversight of medical devices *See Kemp v Medtronic*, 231 F 3d 216, 227 (6th Cir 2000) *cert denied*, 534 U S 818 (2001) (holding approval of changes set forth in a PMA supplement has the same preemption implications as approval of an original PMA submission)

[8] There were approximately 40 PMA supplement applications/approvals for FreshLook related contact lenses before Petitioner purchased the lenses at issue in this case (Parisian Dep Exhibit 7) (R pp 671-673)

which is different from, or in addition to, any requirement applicable under this [Act] to the device, and (2) which relates to the safety and effectiveness of the device or to any other matter included in a requirement applicable to the device under this [Act] " 21 U S C § 360k(a) Unlike certain other regulatory regimes relating to product safety, the MDA does not contain a savings clause that exempts state common law claims from the regulation's preemptive provision Accordingly, "virtually every court which has addressed this issue has concluded that preemption under the MDA extends to state court tort claims " *Scott v CIBA Vision Corp* , 38 Cal App 4th 307, 316 (Cal Ct App 1995), *see also Riegel v Medtronic Inc* , 451 F 3d 104 at 106 (noting that the majority of circuits have concluded that "common law tort actions as to PMA-approved devices are preempted by the FDA"), *Mattingly v Medtronic Inc* 486 F Supp 2d 964 (E D Mo 1997) (applying federal preemption to state product liability claims on the basis that such claims are inconsistent with requirements imposed by the FDA), *Hunsaker v Surgidev Corp* , 818 F Supp 744, 751 (D Pa 1992) (finding that section 360k(a) preempts not only legislatively enacted requirements but also "jury-set standards" which "constitute new requirements which defendants must heed"), *Brooks v Howmedica Inc* , 273 F 3d 785, 796 (8th Cir 2001) ("A jury finding on negligent failure to warn would be premised on the fact that the label was not written in a particular way or did not contain certain information This would be equivalent to a state regulation imposing specific label requirements ") Moreover, since the *Riegel* decision was issued, courts have uniformly found tort claims pre-empted *In re Medtronic Inc Sprint Fidelis Leads Products Liability Litigation*, 592 F Supp 2d 1147, 1152 (D Minn 2009)), *aff'd*, 2010 WL 4026802, *1 (8th Cir Oct 15, 2010) [Since *Riegel*,] courts across the country have

applied Section 360k(a) broadly, preempting all manner of claims from strict products liability and negligence"), *Miller v DePuy Spine Inc*, 638 F Supp 2d 1226, 1229 (D Nev 2009) ("The *Riegel* decision is direct precedent for summary judgment in favor of [defendant] on [plaintiff's] claims based on strict product liability, negligence, and implied warranty "), *Lewkut*, 724 F Supp 2d at 658, *Horowitz v Stryker*, 613 F Supp 2d 271 (E D N Y 2009), *Blanco v Baxter Healthcare Corp*, 158 Cal App 4th 1039, 70 Cal Rptr 3rd 566 (2008), *Parker v Stryker Corp*, 584 F Supp 2d 1298 (D Colo 2008), *Ilarraza v Medtronic Inc*, 677 F Supp 2d 582 (E D N Y 2009), *Despain v Bradburn*, 372 Ark 272, 282 S W 3d 814 (2008) (affirming summary judgment), *McGuan v Endovascular Tech Inc*, 106 Cal Rptr 3d 277, 182 Cal App 4th 974 (Ct App 2010) (affirming summary judgment), *Mullin v Guidant Corp*, 114 Conn App 279, 970 A 2d 733 (2009) (affirming summary judgment), *Raleigh v Alcon Labs Inc*, 403 Ill App 3d 863, 934 N E 2d 530 (2000) (affirming summary judgment), *Sanders v Advanced Neuromodulation Sys Inc*, 44 So 3d 960 (Miss 2010) (affirming summary judgment), *Blunt v Medtronic Inc*, 315 Wis 2d 612, 760 N W 2d 396 (2009) (affirming summary judgment) In South Carolina, finding that a jury verdict is "state action" preempted under the provisions of the MD is a natural application of the Court's decision in *Riegel* and is consistent with prior preceded, see in *Whaley v CSX Transportation Inc*, 362 S C 456, 609 S E 2d 286 (2005) (holding claim against railroad was preempted by federal law and to find otherwise might result in a jury verdict in conflict with federal law)

Petitioner's allegations are necessarily an attack on the FDA's requirements for the lenses, because they attack the design and labeling of the lenses approved by the FDA

through the PMA process *Easterling v Cardiac Pacemakers Inc*, 986 F Supp 366, 374 (E D La 1997) ("once the FDA approves a specific design, that design becomes in effect the FDA requirement") (emphasis added) Courts routinely acknowledge that "any cause of action based on testing, labeling or marketing is preempted by the FDA standards for premarket approval" of a Class III device *Tarallo v Searle Pharmaceutical Inc*, 704 F Supp 653 (D S C 1988) Moreover, the South Carolina District Court has held the MDA "expressly precludes the individual states from establishing requirements different from or in addition to those promulgated by the FDA, [and] reveals on its face the congressional objective to prohibit, by the doctrine of express preemption, the proliferation of multiple, diverse, state by state device requirements" *Stewart v Int l Playtex Inc*, 672 F Supp 907, 909 (D S C 1987) As Judge Anderson explained in granting summary judgment

> Plaintiff's common law tort claim alleging "inadequate warnings" seeks, by definition, to establish a tort labeling requirement which could be different from or in addition to the existing and applicable FDA requirement Therefore, because the following prerequisites are met, the preemption language in § 360k applies The plaintiff here argues South Carolina tort law, which plaintiff hopes will impose a more stringent labeling standard on defendant, is not a "requirement" as used in the regulation Therefore plaintiff maintains the express preemption declaration in § 360k is not applicable in these circumstances Despite plaintiff's assertions to the contrary, the term "requirement" as used in § 360k has been expressly defined by the FDA as *any* standard "having the force and effect of law (whether established by statute, ordinance, regulation *or court decision*)" 21 C F R § 808 1(b) (emphasis added) On its face, this definition encompasses the actions of a court of law entering judgment against the defendant for compensatory and punitive damages based upon "inadequate warnings" The FDA has therefore determined that a state's common law – to the extent it attempts to regulate matters already addressed by the FDA – shall be

> considered a § 360k "requirement " South Carolina tort law is, therefore not exempt from § 360k [P]laintiff sets forth several grounds for his argument that the federal regulations impose only a minimum standard of conduct Plaintiff maintains because a state can apply for an exemption to the preemption mandate, this proves the regulations set forth minimum levels of compliance This is not the case

Id at 909-10 As set forth above, numerous other courts have also held that a failure-to-warn claim is preempted by PMA approval of the medical device *See e g Riegel*, 552 U S at 320-322, 128 S Ct 999, *Brooks*, 273 F 3d at 796

The evidence that these FreshLook contact lenses were and are regulated by the FDA as Class III medical devices is overwhelming and uncontradicted Specifically, FreshLook contact lenses were approved through the PMA Supplement process described above In cataloguing the approval of the PMA application and the supplemental applications to the trial court, CIBA submitted three FDA approval letters approving the applications related to the FreshLook family of contact lenses, along with the testimony of CIBA's Director of Global Regulatory Affairs, the testimony of Weston's own expert (Dr Parisian), and the testimony of Philip Phillips, former FDA Deputy Director of Science and Regulatory Policy for the Office of Device Evaluation

ARGUMENT

I The CIBA Vision FreshLook Color Contact Lenses Allegedly Worn by Petitioner Received Premarket Approval Through the FDA's Premarket Approval Process and Therefore Petitioner's Causes of Action, Which Allege Different Requirements, are Preempted as a Matter of Law

The argument under this heading addresses the following two related "issues presented" by Petitioner in her brief

1 CIBA is entitled to preemption if and only if it received a pre-market approval (PMA) letter for its non-corrective lenses

2 Viewing the evidence, inferences, and ambiguities in the light most favorable to Customer, and construing the same most strongly against CIBA, there is a question of fact as to whether CIBA applied for and/or received PMA approval for its non-corrective lenses

Petitioner attempts to frame the argument in a [partisan] manner calculated to drive the discussion toward her preordained conclusion However, under the *Riegel* framework the relevant inquiry is whether the FreshLook contact lenses allegedly worn by Petitioner received premarket approval through the FDA's PMA process, thereby preempting the causes of action dismissed in the Order granting partial summary judgment Petitioner's entire appeal is predicated on the bald assertion that a specific "PMA letter approving CIBA's non-corrective lenses is the only evidence that is competent to prove federal preemption " (Pet 's Br p 10) (emphasis added) Petitioner's narrow position would effectually impose a state law requirement on the FDA beyond the requirements of the MDA on mandating that the FDA issue self-contained, all-inclusive "letters" for each different version of the same device, regardless of whether there is a safety or efficacy distinction between the versions

A The Contact Lenses Allegedly Worn by Petitioner Fall within the Scope of the FDA Premarket Approval of FreshLook Contact Lenses

As acknowledged by Petitioner's own expert, the initial PMA for the Freshlook lens' first ancestor was issued in 1983, by the FDA (Parisian Dep pp 88-89) (R pp 642-643), 21 C F R § 814 39 FreshLook contact lenses come in several colors and versions spanning the entire spherical power range of -20 00 through +20 00 By 1994, approximately 30 PMA Supplements had been submitted to the FDA, with the FreshLook lenses appearing in PMA Supplement 33 and thereafter [9] (Parisian Dep Exhibit 6) (R pp 667-670) This included submission to the FDA for packaging approval of FreshLook non-corrective (spherical power of 0 00) contact lenses (a/k/a "plano", "non-corrective" or "zero power lenses") (Parisian Dep p 137 and Exhibit 6)[10] (R pp 588, 650, 655& 667-670) This is the same version that Petitioner allegedly obtained in 2004

It is uncontradicted that Petitioner's claims relate to FreshLook contact lenses with UV absorbers as approved in PMA Supplement No 39 (Parisian Dep p 28 and Exhibit 4 (Exhibit 4 "represents what was on her package")) (R p 630, p 655), (Oris Dep pp 65-66 ("Q During the relevant period 'all FreshLook Colors lenses that were manufactured, to be sold in North America were UV?' A 'Yes '")") (R pp 472-473) Because Petitioner's lenses were UV lenses, the FDA approval letter for PMA Supplement No 39 (January 25, 1996) is directly applicable here Moreover, because each related supplement opens all preceding applications for the FDA's full review

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[9] The PMA Supplement approval process has the "same preemption implications as approval of an original PMA submission" *Rattay v Medtronic Inc*, 482 F Supp 2d 746, 758 (N D W Va 2007) (citation omitted)

[10] The FDA has also acknowledged that approval of a range of corrective powers includes approval of the 0 00 power or plano lens Guidance for FDA Staff - Import Alert #86-10, n 1 (R p 754, n 1)

(*supra*, p 12), the FDA approval letter for PMA Supplement 39 also establishes renewal of the prior FDA approvals [11] In January 1996, CIBA obtained approval for a PMA Supplement No 39 to its FreshLook contact lenses for incorporating an ultra-violet absorber into the referenced lenses (*See* FDA FreshLook Colors UV Approval Letter, Parisian Dep Exhibit 8)[12] (R pp 674-678)

Furthermore, on May 7, 1999, the FDA issued a letter approving PMA Supplement No 42 (R pp 671-673) The FDA approval of PMA Supplement No 42 included approval of an additional indication of use (unrelated to correction of visual acuity) to "help protect against the transmission of harmful UV radiation to the cornea and into the eye" (R p 672) (emphasis added) Petitioner's expert, Dr Parisian, acknowledged that UV protection was authorized as an additional claim in PMA Supplement No 42 (Parisian Dep pp 138-139) (R pp 651-652) This specific approval of an additional indication of use unrelated to visual acuity, occurred years before Petitioner obtained the contact lenses involved in this case

Beyond the FDA's specific interaction with FreshLook contact lenses through the PMA process, there was ample uncontradicted evidence before the circuit court and the Court of Appeals that the scope of the PMA approvals covers the plano version, along with the corrective versions of FreshLook contact lenses Specifically, the FDA has

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[11] The record before Judge Cooper also included an August 22, 2003 update to PMA Supplement No 39, which establishes that FreshLook Colors UV contact lenses were approved and regulated as medical devices in 2003 (Oris Dep Exhibit 11) (R pp 627-628)

[12] The FDA approval letter read, in part, "[the FDA] has completed its evaluation of your pre-market approval application (PMA) supplement, which requested approval for incorporating an ultra-violet absorber into the above referenced lenses [FreshLook Colors UV] Based upon the information submitted, the PMA Supplement is approved "

acknowledged that approval of a range of corrective powers includes approval of the 0 00 power or plano lens Guidance for FDA Staff - Import Alert #86-10, n 1 (R p 754, n 1) (noting that the sponsors of contact lenses intended for vision correction and, alternatively, for decorative purposes "voluntarily include a plano lens in the range of corrective powers" described in their device approval submissions) CIBA is one such sponsor as evidenced by (1) its submission of a range including the 0 00 lens (-20 00 to +20 00 powers), (2) submission of package inserts for plano lenses describing indications and uses including "to enhance or alter the apparent color of the eye" (R p 699, middle column),[13] (3) submission of marketing material offering FreshLook Colors contact lenses "whether you have perfect vision or not" (R p 400), and (4) submission of "approved labeling in final print form" bearing 0 00 power (R pp 667-670) *See Kemp* 231 F 3d at 226 ("PMA approval by the FDA constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards and labeling" and "represents the specific federal requirement under [the MDA] to the device " 21 U S C § 360k(a)(1) ") (internal citations omitted)

More generally FDA's pronouncement regarding contact lens oversight also evidences FDA's inclusion of plano lenses within the scope of contact lens products For example, in 1995, the FDA issued a notice including a "comprehensive legal analysis regarding the agency's jurisdiction" over contact lenses 60 Fed Reg 41453 (Aug 11,

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[13] *See also* FreshLook Colors PMA approval Supplement No 47 (November 26, 2002) which (specifically authorized CIBA to move the statement on altering the color of the eye to the "indications" section of the package insert)

[http //www accessdata fda gov/scripts/cdrh/cfdocs/cfPMA/pma cfm?id=2101]

1995) ("FDA Public Notice") At page 16 of the FDA Public Notice, the FDA expressly stated that

> [f]or example, FDA regulates as devices noncorrected tinted contact lenses that are expressly promoted only for their cosmetic effect of enhances eye color because they have physiological effects on the eye See Appendix to Legal Analysis

(emphasis added) (R p 152) In the Appendix to Legal Analysis at p 49 of the FDA Public Notice, the FDA further stated

> Noncorrective Tinted Contact Lenses The agency has taken the position that tinted contact lenses that do not correct or improve vision and are promoted to enhance eye color are medical devices This position is based on the fact that all contact lenses, including neutral lenses, have a physiological effect on the eye

(emphasis added) (R p 155) FDA's Guidance (including that plano lenses fall within a range of powers) and its Public Notices are significant to the issues on appeal because an agency's interpretation of its own regulation is general entitled to great weight *District Memorial Hospital of South-Western North Carolina Inc v Thompson*, 364 F 3d 513 (4th Cir 2004)

B Petitioner's Missing Evidence Argument is Irrelevant and Disingenuous

Petitioner misstates the issue by suggesting (without any authority) that the only proof of premarket approval is a PMA approval letter so detailed that it cannot be parsed by trained legal advocates to have a hint of inconclusiveness [14] The uncontradicted evidence outlined herein and presented to the courts below clearly shows that that the Petitioner's FreshLook contact lenses were within the scope of the premarket

[14] Essentially Petitioner requires that the approval letters issued by the FDA expressly list individually the exact power of the FreshLook lenses allegedly worn by Petitioner Of course had the FDA included this much detail in its letter, Petition would be arguing that the approval letters are insufficient since they do not list the color she selected

applications, submissions, approvals and oversight of the FDA Accordingly, Petitioner's contrived issue and argument is irrelevant Moreover, it is disingenuous In an attempt to dispel her alleged concerns and establish the scope of the PMA approval and FDA oversight to the legally superfluous extent Petitioner asserts, CIBA drafted a letter for the court to send to the FDA (pursuant to the Code of Federal Regulations) specifically asking whether the FreshLook plano (non-corrective) contact lenses were within the scope of FDA's pre-market approval (Transcript p 44, lines 5-25) (R p 304) A copy of the proposed letter to the FDA was filed with the trial court (R pp 167-169) When asked by Judge Cooper for their position on seeking absolute confirmation from the FDA, Weston's counsel called it a "delaying tactic" for which "[w]e've actually filed a frivolous motion letter" (Transcript p 45, lines 1-5) (R p 305) Having succeeded in stopping the court from obtaining absolute confirmation directly from the FDA, Petitioner now inequitably argues that only absolute confirmation directly from the FDA is sufficient for the Court to grant summary judgment (thereby disregarding all the other evidence of pre-market approval and the fact that no evidence to the contrary was submitted by Petitioner) Petitioner cannot be the cause of the "missing" evidence in one proceeding and the victim of it in the next *Hayne Federal Credit Union v Bailey*, 327 S C 242, 251, 489 S E 2d 472, 477 (1997) ("Judicial estoppel precludes a party from adopting a position in conflict with one earlier taken in the same or related litigation "*[w]here a party assumes a certain position in a legal proceeding and succeeds in maintaining that position he may not thereafter simply because his interests have changed assume a contrary position*) *Id* (internal citations omitted) Accordingly, even if there were an inkling of validity in Petitioner's suggestion that absolute

confirmation from the FDA is the only basis for determining the question of law on preemption, Petitioner cannot maintain that argument in light of its prior position before the circuit court against obtaining that such confirmation

II Preemption under the MDA Related to the FreshLook Contact Lenses Allegedly Worn by Petitioner was Sufficiently Established to Justify The Partial Summary Judgment of Petitioner's Preempted Claims and Theories

The argument under this heading addresses the following "issue presented" by Petitioner in her brief

> 3 The Court of Appeals misapprehended how MDA preemption comes into existence and therefore misapprehended the requisite showing for summary judgment on the issue of preemption

Petitioner's arguments boils down to the following A "PMA letter approving CIBA's non-corrective lenses is the only evidence that is competent to prove federal preemption " (Pet 's Br p 10) (emphasis added) Later she further narrows her view of preemption by claiming that "a PMA letter approving a diopter range of lenses that included the non-corrective (zero power) lenses but did not limit the approval to lenses *indicated for the correction of visual acuity* (Pet 's Br p 12) Petitioner does not point to a single case in which a court adopts this position In point of fact, under the framework established by the Supreme Court in *Riegel*, the relevant inquiry for purposes of establishing preemption is whether the CIBA FreshLook contact lenses received premarket approval through the FDA's PMA approval process (See subsection B, *infra*) Under the position advanced by Petitioner, which elevates form over substance, any competent advocate could parse a PMA approval letter for the purpose of avoiding federal preemption

Other plaintiffs making arguments similar to Petitioner have been equally unconvincing For example, in *Pardo v Medtronic Inc* , 2010 WL 5300847 (E D La 2010), plaintiffs brought a product liability action involving a device which transmits electrical stimulation to the spine In response to the defendant's preemption motion, plaintiffs asserted that there exists insufficient evidence to show the device was in fact "approved pursuant to the Premarket Approval process" because the PMA documentation did not individually identify the neurostimulator, but rather the entire system After reviewing the PMA documentation the Court was satisfied that PMA approval and regulatory oversight extended to the unlisted neurostimulator and granted summary judgment *Id* at *2 *Dorsey v Allergan Inc* , 2009 WL 703290 (M D Tenn 2009) further shows the falsity of Petitioner's narrow argument In *Dorsey*, the court addressed a motion for summary judgment on the basis of MDA preemption for a silicon gel implant that was admittedly implanted before the PMA approval letter was issued by the FDA In granting summary judgment, the court noted that the narrow PMA letter issue was a "distinction without a difference" because the proper inquiry after *Riegel* is "whether the FDA has established requirements applicable to the specific device at issue " *Id* at *5

A The FDA's PMA Approval Letters Meet Even the Petitioner's Legally Superfluous Standard for Affirming Summary Judgment on Federal Preemption Grounds

Before further addressing the appropriate elements of MDA preemption, it is worth noting that Respondent did in fact provide the "touchstone" evidence that Petitioner demands In the approval letter for PMA Supplement No 42 (R pp 671-673), the FDA expressly notes that the numerous "Indications" authorized for FreshLook contact lenses included (without any limitation to correcting visual acuity) "FreshLook

Lenses with UV-absorbing monomer help protect against the transmission of harmful radiation to the cornea and into the eye " (R p 672) It is uncontradicted that Petitioner's FreshLook contact lenses included these UV radiation absorbers (*supra*, pp 18-19) For example, Petitioner's own expert, Dr Parisian, acknowledged that the "UV" symbol on Petitioner's contact lens package establishes that her lenses contain the "ultraviolet ray protection ingredient " (Parisian Dep pp 137-140) (R pp 650-653), Similarly, the FDA letter approving FreshLook PMA Supplement No 47 (*supra* at p 20) expressly authorizes the movement of the statement "the lens acts to enhance or alter the apparent color of the eye" to the "indications" section Accordingly, this is yet another PMA approval letter that expressly included an "indicated use" encompassing color lenses and without any limitation to correcting visual acuity Thus, even under the Petitioner's narrow framework, the FDA did in fact issue "touchstone" PMA approval letters meeting Petitioner's self-styled standard for summary judgment in this case

B It is the PMA <u>Process</u> and not Just the Four Corners of the Approval Letters that Establishes Federal Preemption Under the MDA

The United States Supreme Court in *Riegel* that the MDA "imposes a regime of detailed federal oversight " 552 U S at 316 For Class III medical devices (such as Freshlook contact lenses), that regime includes a "rigorous" premarket approval process of an average 1200 hours reviewing multivolume applications, a full report of required studies, and full statements of the devices properties, components, ingredients and principals of operation, device samples, sample packaging, sample package inserts and labeling *Id* at 317-318 The FDA letters approving the application are merely a few pages of this robust PMA approval process In fact, in its PMA letters, the FDA defines "PMA" as the "premarket approval application " ("[FDA] has completed its evaluation of

your premarket approval application (PMA) ") (R pp 671 * 674) The FDA then states in its PMA letters that "based upon the information submitted, the PMA [i e , the application] is approved " (R pp 672 & 674) Thus, the FDA's PMA letters in this case expressly incorporate the applications as relevant to understanding the scope of the approval and insulting preemption For example, the application submitted included blister pack labeling for the plan version of the lenses of the same type allegedly worn by Petitioner (R pp 650, 667-670 & 699)

Under the MDA's express preemption provision (21 U S C § 360k) the first issue is whether the FDA imposes device-specific requirements It does not require each of those specific requirements to be listed in the letter approving the application The PMA approval letters included in the Record on Appeal do expressly state that the approval is for "the devices as modified by your PMA [premarket approval application] " (e g , R pp 672 & 674) Thus, material deviation from the device specific requirements set forth in the application would deviate from the FDA requirements In affirming preemption in *Riegel*, the Supreme Court noted that the Second Circuit found that the device manufacturer was "*clearly subject to the federal device-specific requirement of adhering to the standards contained in its individual federally approved*" premarket approval application" *Riegel*, 552 U S at 321 (emphasis added) [15]

[15] Respondent is not suggesting that everything submitted to the FDA by a sponsor can support preemption, but rather that matters submitted, including specifications in the applications which are incorporated by the FDA or otherwise reflected in the FDA's analysis and determination, are relevant to the scope of preemption *See Lewkut v Stryker Corp* , 724 F Supp 2d 648, 654-56 (S D Tex 2010) ("This court is tasked only with determining what was ultimately approved via the PMA process [and may rely on] public documents released by the FDA in determining what [ ] components were approved ") (emphasis added)

In *Riegel*, "premarket approval" is defined as a "rigorous process" that gives rise to requirements under the MDA 552 U S at 317, 322-23 Courts applying *Riegel* have focused on the process and not just the approval letters *Walker v Medtronic Inc* , 2010 WL 4822135, *4 (S D W Va 2010) ("The PMA process establishes specific requirements applicable to a particular device "), *Lewkut v Stryker Corp* , 724 F Supp 2d 648, 654-56 (S D Tex 2010) (dismissing claims under Rule 12(b)(6) after considering draft package insert, FDA device description, other PMA Supplements, and FDA public records and finding that an unlisted component of surgical device system was included in within the scope of preemption), *Lemelle v Stryker Orthopaedics*, 698 F Supp 2d 668, 674 (W D La 2010) ("The PMA process itself establishes federal requirements for a particular device ") (emphasis added) [16] Even, more compelling here is that Petitioner agreed that the process, not the letter, was the focus for determining MDA preemption when she appealed to the South Carolina Court of Appeals

> Federal preemption arises only if the 'FreshLook Colors' plano lenses were approved by the FDA as 'medical devices' under its pre-market approval (PMA) process prior to the sale of those devices to Customer

(Weston's Initial Brief to the Court of Appeals, p 5) (emphasis added) Thus, for example, express-warranty claims that are based solely on the "contents of an FDA-approved label are expressly preempted by § 360k(a) " *Riley v Cordis Cor* , 625 F Supp 2d 769, 787-788 (D Minn 2009), *Martello v Ciba Vision Corp* , 42 F 3d 1167, 1168-69 (8th Cir 1994) (finding all of the plaintiff's claims, including an express-warranty claim,

[16] Similarly, the circuit court below appropriately considered the package insert, the related PMA supplements addressing issues beyond mere visual acuity, the FDA policy regarding oversight of non-corrective color contact lenses, and the FDA Guidance acknowledging that the FDA considers a range of powers reference for visual acuity to include plano/zero power lenses even though they have no visual acuity impact

to be preempted because they "would add requirements in areas reviewed in the premarket approval process") (emphasis added)

C Petitioner's Proposed Standard for how the FDA Must Draft its PMA Approval Letters Would Create an Invalid State Requirement Under the MDA

The PMA process itself has been accorded the status of all independent federal requirement applicable to a medical device under the MDA preemption analysis For example, the Seventh Circuit has found that "[i]n considering the FDA's preemption regulations under the MDA and the structure of the Amendments, we also concluded that the PMA process constitutes a specific federal requirement for preemption purposes under 21 U S C § 360k(a) " *Mitchell v Collagen Corp* , 126 F 3d 902, 906 (7th Cir 1997), *Riegel*, 552 U S at 323, 128 S Ct 999 ("[Premarket approval] *is* federal safety review ") (emphasis in original)

Petitioner argues that federal preemption can only arise under the MDA if the FDA phrased the PMA approval letters in the specific, narrow terms selected by Petitioner The "magic words" Petitioner argues for are essentially the following "Although the PMA application and the this PMA approval cover a range of contact lens powers [from (-) 20 diopters through (+) 20 diopters], and, although, zero-power lenses fall at the center of that range, as the FDA has previously advised, nevertheless, the FDA, affirmatively states, in order that there can be no misunderstanding, that zero-power lenses fall within the range covered by this PMA approval " Of course, had the FDA gone into this much detail in issuing it's approval, the approval "letter" would be a "book" and Petitioner would have simply invented other magic words Courts presented with such semantic and narrowly focused arguments in other preemption cases have summarily dismissed them See, *e g Stucky v City of San Antonio*, 266 F 3d 342, 343

(5th Cir 2001) (holding that the city "could not simply avoid preemption with mere semantics regarding 'consent' and 'non-consent'") (internal citation omitted)

For this Court to accept Petitioner's argument dictating to the FDA the manner in which it must draft its letters approving PMA applications and restricting the FDA to establishing preemptive oversight only through letters so drafted would itself violate the MDA preemption provisions for all the reasons addressed in *Riegel* and set forth herein Instead, this Court should simply address the relevant legal issue of whether the FDA has established device specific requirements for these FreshLook contact lenses based on the evidence presented to the circuit court, judicial notice of regulatory matters and the relevant case law Rule 56, of the South Carolina Rules of Civil Procedure states that a motion for summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact " Here, the evidence in the record was substantial and uncontradicted, notwithstanding Petitioner's claim that it is not the "right" evidence Petitioner s argument is akin to claiming that the only means of establishing ownership of an item is by submitting the receipt for purchase Of course, ownership can be shown in any number of ways possession, long-time use, a stamped purchase order, a bill of lading, a store cashier's testimony, a store's surveillance camera, tax assessments/payments, or ownership of the raw materials are all ways to establish ownership of an item Indeed, South Carolina courts have long recognized both direct and circumstantial evidence and make no distinction between the weight or value allotted to each Petitioner objects to the circuit court's consideration of affidavits, depositions and expert reports because they are not PMA letters However, they are competent

evidence (some of which Petition relied on herself at the summary judgment hearing) of the PMA process, and to the extent this evidence constitutes expert summaries of the original PMA approval letter and over 40 PMA supplement approval letters it is even within the narrow subject matter scope proposed by Petitioner

For example, Paul Oris, Head of Global Regulatory Affairs for CIBA, the department responsible for the maintenance of all documents relating to the FDA's approval of contact lenses manufactured by CIBA, testified that CIBA's FreshLook Colors lenses received approval from the FDA under the PMA process (Oris 2/28/06 Aff para 3) (R p 702) Consistent with the testimony of both Dr Parisian (Petitioner's expert) and Paul Oris on the application of preemption, Philip Phillips (former FDA Deputy Director, Science and Regulatory Policy, Office of Device Evaluation, Center for Devices and Radiological Health) likewise testified that "FreshLook Colors plano (zero power) contact lenses are approved in the Premarket Approval (PMA) P830037 and the relevant supplements thereto" as Class III medical devices (Phillips Aff paras 2 & 5) (R pp 705-706) Petitioner never contested the expert credentials of Mr Phillips To the contrary, she elicited in his deposition testimony that he had been qualified as an expert in court when he was with the FDA in a medical device case (Phillips Dep pp 19-21) (R pp 690-692) Mr Phillips spent 24 years with the FDA, including service in the Division of Ophthalmic Devices (Phillips Dep pp 28, 34) (R pp 693-694) He testified at his deposition that the information he relied upon to confirm with certainty that the FDA had in fact approved the plano version of the FreshLook lenses and was actively regulating the plano version was information generally relied on by experts in his field (Phillips Dep pp 147, 148, 151) (R pp 695-697)

It is important to note that Petitioner does not claim a factual issue exists because she submitted contrary evidence (e g , a receipt showing that she owns the item, to continue the above analogy), rather, she says that despite all the indicia of preemption that has been produced, she is not convinced because no letter bearing her self selected magic language has been produced This is not the law and Petitioner cannot avoid summary judgment by vague references to "phantom evidence" or artificial issues of fact *Buckner v Sam s Club Inc* , 75 F 3d 290, 292 (7th Cir 1996)

III The Court of Appeals Did Not Usurp the Jurisdiction of the FDA

In her Brief (page 16), Petitioner seizes upon the Court of Appeals' use of the phrase "subject to regulation" by the FDA She then interprets the phrase as "subject to being regulated" by the FDA, but not actually regulated by the FDA From this errant syllogysm, Petitioner posits that because preemption requires PMA approval and constitutes regulation by the FDA, either (1) the Court of Appeals usurped the FDA's jurisdiction and provided the missing PMA approval/regulation (for which it should be reversed) or (2) the Court of Appeals improperly affirmed partial summary judgment in the absence of PMA approval (for which it should be reversed) This false dichotomy does not withstand scrutiny

First, it is contrary to the substance of the Order Second, it is illogical For example, as lawyers, we are "subject to" discipline by this Court Does that mean we are not actually regulated by this Court but only potentially regulated? Of course not The logical application of Petitioner's position is even more absurd in this context because it completely ignores record evidence and the proper role of the judiciary in interpreting statutes and regulations In fact, the decision merely echoes the typical phraseology used by courts addressing preemption, including the United States Supreme Court in *Riegel*

§552 U S at 321 ("Medtronic was clearly subject to the federal, device-specific requirement, ")

A Courts Properly Interpret Statutes and Regulations Within Their Judicial Proper Judicial Function

Petitioner suggests that unless a PMA approval letter refers specifically to the particular lens allegedly worn by Petitioner, the Court may not find preemption This would be abdicating the role of the judiciary It is a fundamental precept of our judicial system that when courts interpret statutes or agency actions they are not encroaching into the purviews of the separate branches, rather, they are fulfilling their constitutional and legal duty *See Breeden v S C Democratic Executive Committee*, 226 S C 204, 209-210, 84 S E 2d 723, 725-726 (1954) (noting that it has been "repeatedly rejected" that "any action by the Court 'would be an encroachment upon the powers of he legislative and executive branches of Government'" (citations omitted)) The duty of judicial interpretation (as opposed to usurpation) has been recognized in South Carolina for 200 years

> 'It is the peculiar and characteristic excellence of the free governments of America, that the legislative power is not supreme, but that it is limited and controlled by written constitutions, to which the Judges, who are sworn to defend them, are authorised to give a transcendent operation over all laws that may be made in derogation of them This judicial check affords a security here for civil liberty, which belongs to no other governments in the world, and if the Judges will every where faithfully exercise it, the liberties of the American nation may be rendered perpetual '

Id (internal citation omitted)

In short, it was appropriate for both the trial court and Court of Appeals to interpret the entire bulk of statutory language, legislative intent, and regulatory requirements presented in the record to determine the legal question of preemption S*ee*

e g State v Perry, 138 S C 329, 136 S E 314, 316 (1927) (holding in the process of interpreting the law, the courts may "construe" together all the sections of the ordinance, [and] judicially interpret its language"), *In re Erickson*, 63 B R 632, 635 (Bankr W D Wis 1986) (holding it is a principle of interpretation that "a statute is to be interpreted, not only by its exact words, but also by its apparent general purpose"), *McCullough v Scott*, 109 S E 789, 795-796 (N C 1921) ([I]n "construing a statute, it is to be considered in its relation to other laws, as part of a general and uniform system of jurisprudence, in connection with other statutes on the same or cognate subjects, or even on different subjects The spirit or reason of the law prevails over its letter ")

B The FDA's Comprehensive Regulation of Medical Devices and FreshLook Lenses Provide Detailed Contours for the Court's Appropriate Exercise of its Judicial Role

Petitioner concedes that all FreshLook "[c]ontacts lenses are a Class III Medical Device under the MDA " (Pet 's Br p 4) Before the FreshLook contact lenses were sold commercially in the United States, they underwent the premarket approval process (Parisian Dep pp 87-89, 94, 112, Exhibits 6, 7, 8, 12, Oris 2/28/06 Aff , Oris Dep pp 38, 123, 152, Phillips Aff paras 5-7) (R pp 641-645, 667-670, 671-673, 674-678, 681-682, pp 701-704, pp 458, 482-483, pp 706-707) In the PMA and PMA Supplement processes, CIBA was required to provide the FDA with assurances that the lenses are both safe and effective (*Id*) The submissions for CIBA's color contact lenses, which include the FreshLook Colors line, are voluminous The FDA employs experts to analyze the submissions and evaluate the safety and efficacy of these Class III devices *See Buckman Co v Plaintiffs Legal Comm* , 531 U S 341 (2001) This analysis includes consideration of the application, clinical data, manufacturing processes, and proposed labeling (21 U S C § 360e(c)), the resulting approval covers these matters

See e g Kemp v Medtronic Inc, 231 F 3d at 226 ("PMA approval by the FDA constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards and labeling ")

Changes affecting the safety and effectiveness of a Class III medical device require detailed documentation and reporting *See* 21 C F R § 814 39 Accordingly, once the device is on the market, it remains subject to extensive and continuing regulation by the FDA *See Brooks v Howmedica Inc*, 273 F 3d 785, 789 (8th Cir 2001) (en banc), *cert denied*, 535 U S 1056 (2002), *McMullen v Medtronic Inc*, 421 F 3d 482, 488 (7th Cir 2005 (discussing post-approval regulation), *see also* 21 C F R §§ 814 80-814 84 In regulating PMA-approved medical devices, the FDA has a wide range of available regulatory measures [17] Petitioner's references to meetings with the FDA regarding the non-corrective versions of the approved FreshLook lenses demonstrates that the FDA was actively engaged in meaningful regulatory oversight of the contact lenses allegedly worn by Petitioner

Against this statutory/regulatory background, the Court of Appeals determined that the FreshLook contact lenses allegedly worn by Petitioner were medical devices under the statutory definition of the MDA, including that they were regulated by the FDA through the premarket approval process and subject to supplemental oversight *Weston v Kim s Dollar Store*, 385 S C 520, 527, 684 S E 2d 769, 773 (Ct App 2009) As noted

[17] *See e g* 21 U S C § 360h(a) (requiring notice to health care professionals), 21 U S C § 360h(b) (requiring a manufacturer to offer repair, replacement, or refund), 21 C F R § 810 1-810 18 (recall authority), 21 U S C § 332 (injunctions), 21 U S C § 333 (penalties), 21 C F R §§ 17 1-17 54 (penalties), 21 U S C § 334 (seizure), 21 U S C § 360e(e), 21 C F R § 814 46 (PMA revocation or suspension)

in the Legal Framework section, *supra*, this was a question of law for the court In support of its conclusion, the Court of Appeals cited *Griggs v S C Elec & Gas Co* , 320 S C 127, 129, 463 S E 2d 608 (1995) In *Griggs*, this Court interpreted the Federal Copyright Act The question before the Court was whether the scope of the Act would encompass a single cooking recipe published by defendant as part of a contest Under the motion to dismiss standard, this Court found that the scope of the Act did encompass the recipe and that plaintiff's cause of action was preempted under the Act The Court of Appeals performed a similar legal interpretive analysis in this case Such an analysis does not usurp the authority of the FDA

The decision of the Court of Appeals in *Brooks v Northwood Little League Inc* , 327 S C 400, 489 S E 2d 647, (Ct App 1997) is similarly instructive In *Brooks*, the Court was called on to interpret the scope of legislation defining the phrase "recreational purpose" to include numerous listed specific activities and "summer and winter sports " *Id* at 648-49 A fact question arose within this legal issue as to whether the legislation (Section 27-3-29(c)) included T-ball In supporting summary judgment, the Court of Appeals held that "[e]ven though section 27-3-20(c) does not expressly list "T-ball" as a recreational purpose, T-Ball qualifies as a "summer sport " *Id* at 651 The Court of Appeals noted that its legal interpretation "gives effect to legislative intent in light of the purposes the statute was meant to achieve " *Id* at 650-51

In the realm of Class III medical devices, it is appropriate for courts to interpret the scope of the FDA's regulatory requirements *See Lewkut v Stryker Corp* , 724 F Supp 2d 648, 654-56 (S D Tex 2010) ("This court is tasked [ ] with determining what was ultimately approved via the PMA process "), *Gomez v St Jude Med Daig Div Inc* ,

442 F 3d 919, 930 (5th Cir 2006) ("The FDA, through the PMA process, has imposed a set of specific regulations on medical devices and their manufacturers that preempt state-law claims ") This includes whether a particular version or model of a device is included within the scope of PMA approval *Rogerson v Telectronics Co* , 1998 WL 559788 (N D Ill August 25, 1998) (granting summary judgment after noting that "we must first determine whether the Model 8224 pacemaker at issue is PMA approved")

In analyzing the relevant statutes and specific regulations/requirements of the FDA, including its letters approving PMA applications, the views and actions of the FDA regarding the device are given appropriate deference *See e g* , *PLIVA Inc v Mensing*, 131 S Ct 2567, 2575 (2011), *Crescent Mfg Co v Tax Com'n*, 129 S C 480 124 S E 761 (1924) ("in interpreting an ambiguous statute the question is what the words meant to those using them ") In this case, the FDA's Guidance acknowledges that a range of powers for contact lenses correcting visual acuity is considered to include non-corrective/plano lenses (R p 754, n 1) The fact that the FDA approved the FreshLook contacts package insert which includes language stating "to enhance or alter the apparent color of the eye" as an independent indication/use further demonstrates that the regulatory context includes all versions within the range regardless of their exact power level (R p 699, middle column) [18] In addition, the approved FreshLook contact labeling in final print form bears "0 00 power" (i e labeling for plano lenses) (R pp 667-670)

Thus, although in the abstract a range could theoretically be argued to exclude a particular point, that is not the case here Courts are often called upon to place words in

[18] PMA Supplement No 47 (specifically authorizing CIBA to make "alter the apparent color of the eye" an identified indication of use)

their appropriate regulator context without usurping the role of the agency *See e g Chevron U S A Inc v Nat Res Def Council Inc*, 467 U S 837, 861(1984) ("The meaning of a word must be ascertained in the context of achieving particular objectives ") In *Chevron*, the United States Supreme Court interpreted the word "source" as it is variously used by the EPA The Court interpreted it "not in a sterile textual vacuum, but in the context of implementing policy decisions in a technical and complex arena " *Id* at 863

C Even Assuming Non-Corrective Lenses Were Not Subject to PMA Approval Marketing a Non-Corrective Lens is Not Actionable

Even assuming, *arguendo*, that Petitioner is correct that the only competent evidence of preemption is the FDA letters of approval and that such letters must be read so narrowly as to exclude from their terms the lenses allegedly worn by Petitioner, her claims are still preempted under the MDA Petitioner concedes that a FreshLook contact lens at power 0 01 falls squarely within her own interpretation of the FDA PMA approval letters Petitioner also concedes that these PMA approval letters were issued well before she allegedly obtained a pair of FreshLook lenses Thus, under Petitioner's argument, even though only a slight modification, a 0 00 power lens falls outside the strictest terms of the PMA letters However, it does not follow that the lenses fall outside the reach of preemption First, manufactures may make changes to approved devices that do not affect the safety or effectiveness of the device *Riegel*, 552 U S at 312 More importantly, if the PMA approval imposed requirements on CIBA to produce only FreshLook contact lenses with corrective powers (which it does not), then the production of non-corrective FreshLook contact lenses would be a violation of the FDA requirements applicable to the approved device Producing a version of an approved

device that violates an FDA requirement does not destroy preemption *See Buckman Co* 531 U S at 349 n 4, *McMullen v Medtronic*, 421 F 3d 482, 487-88 (7th Cir 2005), *Delaney v Stryker Orthopaedics*, 2009 WL 564243, *4 (D N J 2009) Under the Petitioner's own theory, the plano lens version (0 00 power) is either so slightly different from the concededly approved 0 01 power version that separate approval is not required, or else the slightly modified version is in violation of the FDA requirement applicable to the approved device Either way, preemption continues to apply and Petitioner may not maintain the causes of actions that were subject to the order granting partial summary judgment

D Summary Judgment Should Not be Reversed Without Guidance from the FDA

Although the basis for preemption under the MDA as to the FreshLook contact lenses allegedly worn by Petitioner is overwhelming recounted herein, if this Court is inclined to reverse summary judgment, Respondent respectfully requests that this Court first seek clarification from the FDA

21 CFR § 808 5 expressly allows any state to request an advisory opinion from the FDA with respect to matters concerning preemption of state or local device requirements (R pp 163-64) Such a request should be in the format set forth in 21 CFR § 10 85 (R p 165) The draft letter Respondent previously prepared for the circuit court might be useful to this Court if it decides to seek guidance from the FDA on these issues (R p 167-69)

In evaluating whether it would be worthwhile to seek guidance from the FDA to support reversal of partial summary judgment, the case of *Horn v Thoratec Corp*, 376 F 3d 163, 178 -179 (3rd Cir 2004) may be instructive

> The FDA's views in its *Amicus Curiae* Letter Brief in this case echo the opinion it has voiced in another recent case In a brief submitted to the Circuit Court of Tennessee in *Murphree v Pacesetter, Inc et al* the FDA expressed concerns about the consequences of *not preempting* state common law claims such as Horn's
>
> [I]t is inappropriate for a jury to second-guess FDA's scientific judgment on such a matter that is within FDA's particular expertise FDA determines the scope of a device, including the components it comprises, and the appropriate regulatory pathway for the device FDA subsequently determines whether the device meets the PMA approval standard The agency makes a reasoned and deliberate decision as to the correct pathway of regulation and whether to approve the device Juries lack the scientific knowledge and technical expertise necessary to make such judgments
>
> [T]he prospect of hundreds of individual juries determining the propriety of particular device approvals, or the appropriate standards to apply to those approvals, is the antithesis of the orderly scheme Congress put in place and charged the FDA with implementing
>
> Such uncertainty as to the status of medical devices would create chaos for both the regulated industry and FDA
>
> Statement of Interest of the United States of America at 7-9, *Murphree v Pacesetter Inc et al* No 005429-00-3 (Tenn Circuit Ct Dec 12, 2003)

In sum, clarification from the FDA could be relevant to substantiating the grounds for affirming summary judgment However, because the Petitioner objected to the circuit court contacting the FDA and threatened Respondent with frivolous motion sanctions for suggesting it, (Transcript p 45, lines 1-5) (R p 305), this option should only be pursued if the Court is inclined to reverse summary judgment

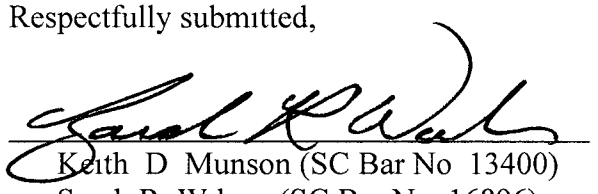
CONCLUSION

All FreshLook Colors lenses manufactured by Respondent CIBA have undergone and received approval from the FDA under the PMA approval process (Parisian Dep pp 87-89, 94, 112, Exhibits 6, 7, 8, 12, Oris 2/28/06 Aff, Oris Dep pp 38, 123, 152, Phillips Aff paras 5-7, Order pp 6-10) (R pp 641-645, 667-670, 671-673, 674-678, 681-682, pp 701-704, pp 458, 482-483, pp 706-707, pp 6-10) All versions of FreshLook contact lenses constitute Class III Medical Device and are actively regulated by the FDA and subject to federal preemption This includes the contact lenses allegedly worn by Petitioner

Rule 56, SCRCP, states that a motion for summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact " Here, the evidence of preemption in the record was uncontradicted (Merely demanding different evidence is not sufficient to defeat summary judgment) Moreover, Petitioner cannot avoid summary judgment by vague references or artificial issues *Buckner*, 75 F 3d at 292

Once the legal question of preemption was resolved by the court, Petitioner had no viable claim with respect to the causes of action subject to the partial summary judgment motion Consequently, there is no set of facts (genuine, material or otherwise) on which Petitioner can prevail, and therefore summary judgment was appropriate and required

Respectfully submitted,



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Dated November 7, 2011
Greenville, South Carolina

THE STATE OF SOUTH CAROLINA
In the Supreme Court

APPEAL FROM RICHLAND COUNTY
In The Court of Common Pleas

James R Barber, III, Circuit Court Judge
G Thomas Copper, Jr , Circuit Court Judge

Opinion No 4592 (S C Ct App Filed July 15, 2009)

Monica Weston, **Petitioner**

v

Kims Dollar Store and
CIBA Vision, a division of Novartis Company Respondents

PROOF OF SERVICE

The undersigned hereby certifies that, on the 7 day of November, 2011, (s)he delivered a copy of the attached **BRIEF OF RESPONDENT CIBA VISION** to the person(s) hereinafter named, at the place(s) and address(es) stated below, via U S Mail, which is/are the last known address(es)

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