

June 19, 2020

Via electronic mail

The Honorable Jenny Abbott Kitchings
Clerk of Court
The South Carolina Court of Appeals
1220 Senate Street
Columbia, SC 29201

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Jun 19 2020
SC Court of Appeals

RE: *Opternative v. S.C. Board of Medical Examiners*
Appellate Case No. 2018-000326
Our File No. 049516/01500

Dear Ms. Kitchings:

I write to update the Court on recent developments that may bear on this appeal and which demonstrate that this appeal continues to present a “live” case or controversy for this Court’s consideration. Specifically, Appellant wishes to update the Court on its regulatory status with the FDA as previously discussed in Appellant’s August 9, 2019 Motion to Stay Appeal, which this Court denied on August 30, 2019.

The background for this letter was explained in Appellant’s Motion to Stay. *See* Mot. Stay 1–2 (attached hereto as Ex. A). In brief, Appellant filed this case on October 20, 2016, challenging the constitutionality of the Eye Care Consumer Protection Law, which bans South Carolina physicians from using Appellant’s online vision testing software to prescribe corrective lenses. The case is now before this Court on appeal from the trial court’s January 26, 2018 order dismissing the case for lack of standing.

For the duration of this case, including when this appeal was filed, Appellant’s software was registered with the FDA as a Class I medical device. *See* 21 C.F.R. § 886.1150. But on July 28, 2019, the FDA informed Appellant that its software did not appear to be properly classified and that Appellant would need to cease marketing its software until it could submit a revised application and obtain a proper classification. Accordingly, Appellant temporarily suspended domestic marketing and began working on a revised application.

Two subsequent developments indicate this Court’s consideration and resolution of the instant appeal is still warranted. First, Appellant has resumed marketing and operations in response

to updated FDA guidance. In April 2020, the FDA issued emergency guidance “to provide a policy to help expand the capability of remote ophthalmic assessment and monitoring devices to facilitate patient care while reducing patient and healthcare provider contact and exposure to COVID-19 during this pandemic.” *Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the Coronavirus Disease 2019 (COVID-19)*, FDA 1 (April 2020), available at <https://www.fda.gov/media/136733/download> (last visited June 13, 2020) (attached hereto as Ex. B). The guidance allows Appellant to market its software domestically for “use of the [software] for a telemedicine consultation, allowing [an] eye care provider to assess specific ophthalmic parameters remotely.” *Id.* at 5. Accordingly, Appellant has resumed operating in dozens of states across the country and would resume operating in South Carolina but for the Eye Care Consumer Protection Law challenged in this proceeding.

Second, when Appellant filed its Motion to Stay, Appellant projected it would submit a revised application for classification by summer 2020 and that it would receive a decision by winter 2020. Due to recent developments, Appellant now projects that it will submit a revised application by winter 2020 and receive a decision by spring 2021.

In sum, Appellant is currently operating under the FDA’s emergency guidance, plans to apply for permanent FDA classification this winter, and continues to have a concrete interest in operating in South Carolina—and therefore, in this appeal.

Very truly yours,



Miles E. Coleman

CC: (by electronic mail):
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