AMERICAN OPTOMETRIC ASSOCIATION
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Via Courier

Robin Newman, MSN, EdD
Director, Office of Compliance
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
WO66-3521
Silver Spring, MD 20993-0002

Re: Opternative: Marketing of Unapproved and Uncleared Ophthalmic Device

Dear Dr. Newman:

The American Optometric Association (AOA) submits this complaint concerning a new medical device marketed by Opternative, Inc. (Opternative). The device is marketed directly to consumers as an online "eye exam" that is claimed to provide a prescription for eyeglass or contact lenses "as accurate as an in-person refractive eye exam." Although it poses significant health risks to consumers and is not substantially equivalent to any currently marketed device, the Food and Drug Administration (FDA) has never reviewed the safety or efficacy of the device or the promotional claims made for the device in its labeling.

The Opternative device relies on unproven technology that has never, to our knowledge, been shown to be safe or effective in accurately determining a lens prescription. Specifically, the device relies on new, self-administered tests of visual performance to generate a prescription, rather than on assessment by an eye care professional of the underlying eye conditions affecting vision. There are many reasons to doubt the accuracy of prescriptions generated by this approach. Worse yet, use of the device will result in the forgoing of an examination by an eye doctor that is designed to detect a variety of conditions that could affect vision or general health and that require medical treatment.

AOA respectfully requests action from the CDRH Office of Compliance ("OC") to address this situation. CDRH does not appear to have ever classified, cleared, or approved the Opternative device or any other device that relies on similar technology to generate a lens prescription. Thus, marketing of the device by Opternative violates the Food, Drug, and Cosmetic Act (FDCA). The violation is particularly serious given the significant public health concerns raised by use of the device. We therefore respectfully urge OC to take prompt action before the eyesight and/or health of any consumer is permanently impaired or lost.

I. BACKGROUND

Opternative's website (www.Opternative.com) asserts that the device in question provides users with an "online refractive exam that provides a prescription for glasses and contacts."[1] Such a prescription is needed when defects in the overall shape of the eye, defects

[1] Content of www.opternative.com (accessed Mar. 21, 2016) (Attachment 1).

in the shape of the cornea, or defects in other structures of the eye cause errors in the way light is focused on the retina, called refractive errors.

A. SUBJECTIVE REFRACTION

Normally, an eye exam involves a physical examination of the eye and a process for identifying the underlying defects that cause refractive errors. The examination, performed by an eye doctor, is designed to determine the type and degree of correction needed for such errors. This is an empirical, interactive process during which the patient is asked to look through various lenses and combinations of lenses, subjectively identifying which lens or combination results in the best vision. Significantly, a standard refractive exam also includes a process of ruling out serious eye conditions that require medical treatment beyond a lens prescription. These conditions include diseases that could affect both vision and general health.

B. OPTERNATIVE'S UNPROVEN REFRACTION METHODS

Opternative's method of refraction appears to rely on a series of tests that use eye charts displayed on the user's personal computer and smart phone, along with other information entered by the user. This method is described on the Opternative website and in a patent application filed by Opternative.[2] It was also evaluated by AOA by using the device.[3] Some of the eye charts used by Opternative appear to be modified versions of eye charts commonly used in the practice of optometry and ophthalmology; others appear to be entirely new eye charts developed by Opternative.

1. Distinguishing myopia (nearsightedness) and hyperopia (farsightedness)

In one test, the Opternative device displays two eye charts simultaneously on the user's computer and smart phone. The chart on the computer has black letters on a green background while the chart on the smart phone has black letters on a red background. The Opternative device then asks the user which chart appears sharper.[4]

This appears to be a test for determining whether the user has myopia (commonly known as nearsightedness, which is corrected with a concave lens) or hyperopia (commonly known as farsightedness, which is corrected with a convex lens). According to discussion of a similar set of charts in Opternative's patent application, a selection that the chart with the green background is sharper suggests that the user has hyperopia.[5] This appears to be a novel use of a Duochrome Test, which is typically used to determine whether a prescription to correct myopia or hyperopia should be refined, not to determine whether the patient has myopia or hyperopia in the first instance.

Opternative also attempts to ascertain if the individual is nearsighted or farsighted by asking for details about the user's prior lens prescription and by asking whether the user experiences eye strain during near or distance viewing activities.[6] Most refractive errors that

[2] U.S. Patent No. 9,237,842 (filed Mar. 3, 2014) (Attachment 2)
[3] Screen Shots Taken During Use of the Opternative Device (www.opternative.com/onboarding/health?exam_type_id=35)(accessed Mar. 1, 2016) (Attachment 3).
[4] Attachment 3, at 84-85.
[5] Attachment 2, at 21:19-21:37
[6] Attachment 3, at 88-92.

require correction are asymptomatic, however. These errors of refraction cannot be determined by self-report of symptoms.

2. Determining strength of correction for myopia or hyperopia

In a second test, Opternative displays multiple versions of an eye chart with a single row of characters. The characters appear at different sizes in each version. The charts are displayed on the patient's computer and have a row of black characters on a white background, such as a row with three black Os and one black X. The size of the characters decreases as different versions of the chart are displayed. At each size, Opternative asks the user to identify the character that looks different from the rest.[7]

This appears to be a test for determining the strength of correction needed for myopia or hyperopia. According to Opternative's patent application, this test can be used to determine the smallest size at which the characters can be correctly identified when viewed from a certain distance.[8] The patent application asserts that this information can be used to calculate the strength of the correction needed for myopia or hyperopia.[9] However, the patent application does not disclose the precise method for doing so, and AOA is not aware of any such method that is established and accepted.

3. Determining axis of astigmatism

In a third test, the Opternative device displays multiple versions of an eye chart with parallel lines, which appear at different angles in each version. These charts are displayed on the user's computer. They have sets of white parallel lines on a black background. The angle of the lines changes as different versions of the chart are displayed. Each time the lines appear at a new angle, the Opternative device asks the user to identify any lines that appear sharper.[10]

This appears to be a test for determining the axis of correction needed for astigmatism, a defect in the curvature of the cornea that causes distortion of vision along a certain angle. According to discussion of a similar set of charts in Opternative's patent application, a user with astigmatism will see the lines around the axis of the astigmatism (i.e., the angle of distorted vision) as bolder or better in focus than the other lines.[11] Charts like these are sometimes used to estimate the axis of astigmatism, but there is no evidence that they can be used to estimate the axis with an accuracy greater than ± 30 degrees, and they are not relied on to finalize a prescription.

4. Determining strength of correction for astigmatism

In a fourth test, the Opternative device displays multiple versions of an eye chart with two triangles separated by a space. The space between the triangles gets smaller in each version. These charts are displayed on the user's computer and have two green triangles on a black background. They appear to be positioned along the axis of astigmatism determined previously, with the bases of the triangles lined up against each other and separated by the space. The size of the space decreases as different versions of the chart are displayed. Each

[7] Attachment 3, at 52-76.
[8] Attachment 2, at 19:30-20:40, 33:38-33:58.
[9] Attachment 2, at 33:49-33:53.
[10] Attachment 3, at 114-128.
[11] Attachment 2, at 16:19-16:24.

time that a new version appears, the Opternative device asks the user to select whether any blurring around the edges of the triangles appear to touch at all.[12]

This appears to be a test for determining the strength of correction needed for astigmatism. The test seems to be based on the fact that astigmatism distorts, or stretches, the patient's vision along the axis and therefore causes a patient to see blurring around the edges of the triangles that are lined up against each other. The degree of blurring depends on the severity of the patient's astigmatism, so that the size of the space at which the blurring appears to touch will be larger for a patient with more severe astigmatism and smaller for a patient with less severe astigmatism. According to discussion of a similar set of charts in Opternative's patent application, the size of the space can be used to accurately determine the strength of correction needed for astigmatism.[13] Once again, however, the patent application does not disclose the precise method for doing so, and AOA is not aware of any such method that is established and accepted.

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After a user completes these and other tests and provides additional information, the Opternative device generates a prescription that is signed by a practicing ophthalmologist licensed in the state of the user's residence. The user then receives the signed prescription via email, which can be filled at the retail outlet of his or her choice.

II. OPTERNATIVE'S DEVICE IS ADULTERATED AND MISBRANDED

The FDCA requires clearance of a 510(k) premarket notification or approval of a premarket approval application (PMA) prior to the commercialization of a device unless the device (1) is of a type which has been previously classified into class I or class II, and (2) has been determined to be exempt from the 510(k) requirement. 21 U.S.C. § 360(k)-(m), 360c(f), 360e(a). Failure to obtain required clearance or approval makes a device adulterated and misbranded. Id. §§ 351(f), 352(o).

Opternative's product meets the statutory definition of a device. It is intended for use in the diagnosis of eye conditions that cause refractive errors, a prerequisite to the generation of a prescription for eyeglass or contact lenses to correct those errors. See id. § 321(h)(2) (defining a "device" as an article "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, . . . which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes").

AOA has found no record of any cleared 510(k) premarket notification or approved PMA for the device. Instead, Opternative merely registered as a specification developer for a visual acuity chart (21 C.F.R. § 886.1150), color vision tester (21 C.F.R. § 886.1170), and medical device data system (21 C.F.R. § 880.6310).[14] Devices covered by those classification regulations are exempt from the 510(k) requirement.

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[12] Attachment 3, at 131-140.

[13] Attachment 2, at 23:33-23:40, 24:29-24:30.

[14] See 2015 Establishment Registration and Device Listing for Opternative, Inc. (accessed Feb. 23, 2016) (Attachment 4). While Opternative's registration and device listings were current in 2015, the company does not appear to be registered as a manufacturer or specification developer of any devices in 2016.

Based on this information, we presume that Opternative is marketing the device without FDA clearance or approval under the theory that its device falls within 510(k)-exempt classifications because, among other things, it uses one or more visual acuity charts to test a user's vision and generate a lens prescription. If this is Opternative's theory, it is entirely flawed. The intended use of Opternative's device and the technology it uses are far different from those of a visual acuity chart or any other legally marketed ophthalmic device. In addition, the device is intended to replace the judgment of an eye care professional in prescribing lenses and raises significant new questions of safety and effectiveness. Thus, the device cannot lawfully be marketed without prior review and clearance or approval by CDRH.

A. THE DEVICE DOES NOT HAVE THE SAME INTENDED USE AS PREVIOUSLY CLASSIFIED VISUAL ACUITY CHARTS

A device is properly marketed under an existing classification regulation only if it has the same intended use as other legally marketed devices covered by the regulation. Opternative's device may not be marketed under the classification regulation for visual acuity charts because its intended use is different from charts previously marketed under that regulation. See, e.g., 21 C.F.R. § 886.9(a) (excluding from the scope of the 510(k) exemption for visual acuity charts any device "intended for a use different from the intended use of a legally marketed device in that generic type of device").

A visual acuity chart, under the existing classification regulation, is "a device that is a chart, such as a Snellen chart with block letters or other symbols in graduated sizes, intended to test visual acuity." 21 C.F.R. § 886.1150. The term "visual acuity" refers to a person's visual performance, meaning the person's ability to discern detail or to recognize detailed targets. Thus, most visual acuity charts are used to "determine the smallest symbols, letters, or words that can be identified correctly."[15] Visual acuity is commonly expressed in terms comparing the patient's vision to what a "normal" person is able to see from a certain distance. Thus, for example, a person with 20/20 vision can read at twenty feet what a normal individual can read at twenty feet. A person with 20/80 vision has poorer quality vision, because the person needs to be twenty feet away to see clearly what the normal person can see clearly from eighty feet away.[16]

Testing visual acuity, which is the intended use of a visual acuity chart, is fundamentally different from determining a prescription for eyeglass or contact lenses, which is the intended use of Opternative's device. The former involves measurement of a person's visual ability; the latter requires identification of the type and degree of correction needed when the measured ability is less than normal.

As an analogy, testing visual acuity is like testing a patient's cardiovascular function by asking a patient to walk on a treadmill and recording his or her heart rate. To carry the analogy further, using the result of a visual acuity test to determine a lens prescription is like using the measured heart rate to determine that a patient needs a certain type of heart surgery. In both situations, the results of the testing must be carefully interpreted and analyzed before any treatment recommendation can be made.

In addition, visual acuity charts are ordinarily used by an eye care professional examining a patient, while the Opternative device is intended for use and self-diagnosis by the

[15] Benjamin WJ, Borish's Clinical Refraction, 2d Edition, at 217-18 (2006).
[16] Richard Kolker, Subjective Refraction and Prescribing Glasses (Nov. 2014).

patient without the involvement of such a professional. That alone is sufficient to make the Opternative device ineligible for marketing under the 510(k) premarket notification exemption for visual acuity charts. See 21 C.F.R. § 886.9(a) (noting that a "device is intended for a use different from the intended use of a legally marketed device in that generic type of device" if, e.g., "the device is intended for lay use where the former intended use was by health care professionals only").

B. THE DEVICE'S UNPROVEN TECHNOLOGY RAISES SAFETY AND EFFECTIVENESS ISSUES THAT HAVE NOT BEEN CONSIDERED BY CDRH

Further, Opternative's device may not be marketed under the classification regulation for visual acuity charts or any other existing classification regulation because the device uses new technology that raises questions of safety and effectiveness unlike those associated with any ophthalmic device previously considered by CDRH. Technology raising different issues of safety and effectiveness from legally marketed devices must be reviewed by CDRH in the context of a PMA or de novo request for classification before being marketed. See 21 U.S.C. § 360c(f)(1)(A), (i)(1)(A).

The new safety and effectiveness issues raised by Opternative's device include:

1. Potential for inaccurate prescriptions that could harm patients

First, the device relies on users to self-administer a variety of visual tests. This is a significant difference from tests currently used in the generation of lens prescriptions, which are administered by a trained eye doctor. It raises critical questions about whether users are capable of following the directions, administering the tests correctly, and generating reliable results with the device. See, e.g., FDA, Guidance for Industry and FDA Staff: The 510(k) Program—Evaluating Substantial Equivalence in Premarket Notifications 18 (July 28, 2014) (noting that a change in the clinical context or setting of device use may preclude a finding a substantial equivalence to a predicate device).

Second, the device relies on several new technologies, as Opternative appears to have itself recognized by filing a patent application for the device. These appear to include modified versions of eye charts already used in the practice of optometry and ophthalmology, as well as entirely new eye charts developed by Opternative. The new technologies also appear to include new ways of interpreting the results obtained with the charts, such as unconventional use of Duochrome Test results to determine whether a user has myopia or hyperopia, novel methods for calculating the strength of correction needed for myopia, hyperopia, or astigmatism from visual test results, and a crude method for determining the axis of astigmatism, rather than determination of these prescription parameters directly through subjective refraction. AOA's ability to review the potential constraints of this technology is restricted because Opternative has not fully disclosed details about the device's design and operation. However, we are not aware of any published research to support the idea that Opternative's methodology can replace the need for subjective refraction with a lens refractor assembly or other lenses.

A preliminary review has identified several specific issues that underscore the need for full and complete investigation of the device by CDRH. These include the facts that:

- The device's method for determining the strength of correction needed for myopia or hyperopia could be prone to error because it relies on the user to identify only one distinct character per line of characters displayed. The common practice is to require

that the patient identify every character on each line in order to increase sensitivity of the testing and reduce the chance that the patient could easily guess correctly.

- The device's method for determining the axis of astigmatism appears to have an accuracy of ± 30 degrees. This amount of variation significantly exceeds the level that would be acceptable for subjective refraction.

- Opternative makes some attempts to standardize the way the tests are administered, but it is inherently difficult to assure that users can adequately do so. As an example, the device's only control for glare, which affects visual acuity, is an instruction to turn down room lights and close window blinds. There is no assurance, however, that this is adequate to mitigate the potential effects of glare on prescription accuracy.

- Ambient light in the user's environment, the backlighting of the user's computer screen and smartphone display, and other characteristics of the computer and smartphone (such as resolution, brightness, and contrast) could affect accuracy of the test results, especially for tests where enlargement of the pupil is needed.

- The accuracy of calculations made by the device depends on the accuracy of information about the user's distance from his or her computer screen during testing.[17] These calculations could be prone to error because the device uses an imprecise method to estimate distance from the screen—asking the user to enter a shoe size and stand a certain number of foot-lengths away from the screen.

All of these factors suggest that Opternative's device is not equivalent to existing methods and should not be relied upon as the basis for an accurate final prescription. Indeed, the filing of a patent application belies any argument by Opternative that its method is substantially equivalent to prior marketed devices. Additional technical information about these and other issues is provided in the attached appendix.[18]

Third, the device does not appear to incorporate any technology for assessing the user for conditions that cause refractive errors related to a person's ability to perceive and maintain a single clear image when viewing the world with two eyes. These errors must be corrected with a prescription for lenses with a prism component, but it is not clear how, if at all, the Opternative device determines whether this component is needed.

Opternative's website disregards these and other concerns about accuracy by claiming that its device is "As Accurate as an In-Person Refractive Eye Exam" and citing a clinical study to support the claim.[19] Limited details about the study are provided on the website, but those details suggest that the study is insufficient. This is primarily because the website presents accuracy results with respect to only one specific component of a typical prescription—negative sphere power (i.e., the strength of correction for myopia). There are no results for accuracy with respect to positive sphere power (i.e., the strength of correction for hyperopia), axis for astigmatism, cylinder for astigmatism, or other components of a typical prescription. Without

[17] See Attachment 2 at 11:16-11:18.
[18] Appendix of Technical Considerations Related to Safety and Effectiveness of the Opternative Device (Attachment 5).
[19] Attachment 1, at 9.

data demonstrating accuracy with respect to all components of a prescription, it is impossible to know whether the Opternative device is indeed as accurate as subjective refraction.

AOA's concern is that users relying on inaccurate prescriptions generated by Opternative's device may experience a range of negative impacts, from eye fatigue, intermittent diplopia (double vision) and to adverse impact on reading comprehension. For example, it is critical that the astigmatic portion of a refraction be as precise as the spherical portion for the patient to have best vision possible with no eye strain. In particular, over- or under-correcting astigmatic error and its axis in a lens prescription is detrimental to the patient and may cause serious disability, especially while driving at night or by unknowingly reducing reading efficiency and comprehension.

2. Potential for misdiagnosis of serious eye conditions that affect vision

A number of underlying conditions or diseases, which would be apparent to a clinician performing an in-person refractive exam with previously classified ophthalmic devices, are likely to be misdiagnosed by Opternative's device as a refractive error requiring a lens prescription—or missed entirely. AOA is concerned that use of the Opternative device will result in harmful delay in the diagnosis of such eye diseases as glaucoma, cataracts, and macular degeneration. These conditions would be identified in an eye examination by an optometrist or other qualified eye doctor.

In addition, the Opternative device does not appear to take adequate account of undiagnosed or uncontrolled diabetes, which can cause an accumulation of fluid in the eye. This, in turn, can cause significant but temporary refraction errors that mimic those cause by myopia or hyperopia. Because the device relies on technology that does not appear able to distinguish between refractive errors caused by complications of diabetes versus refractive errors caused by myopia or hyperopia, there is potential for the device to generate a lens prescription when the patient should instead be treated for an underlying blood sugar imbalance or other serious disorder.

Opternative purports to apply exclusion criteria to prevent use of the device by high risk populations,[20] but the exclusion criteria are likely insufficient to protect the public from harm and should be thoroughly vetted by CDRH. Additional exclusions are required that relate to accommodation and vergence. One must also question the effectiveness of exclusion criteria that rely entirely on self-reporting, with no additional checks.

FDA has expressed concerns about prescription of hearing aids without evaluation of the patient by a qualified doctor.[21] The same sort of concerns apply here. At a minimum, FDA review is required to determine that extent to which the Opternative device may put users at risk of an erroneous prescription or a failure to diagnosis a serious medical condition.

[20] Attachment 1, at 93.
[21] 21 C.F.R. § 801.421(a)(1).

3. Generation of a prescription with limited or no meaningful input by a trained eye doctor

As noted above, the Opternative device differs from previously classified devices because it enables users to self-administer visual tests without any involvement of a trained eye doctor. The device differs for the additional reason that it also appears to perform most, if not all, test interpretation without any provider involvement.

Opternative's website asserts that an ophthalmologist reviews each user's results and then issues a prescription.[22] However, it is not clear what details are provided to the ophthalmologist or how the ophthalmologist could use the results obtained directly from the tests to independently develop a prescription or confirm its accuracy. To the contrary, insofar as the ophthalmologist never physically examines the patient, it seems that the ophthalmologist cannot serve as a significant safeguard for the patient. Because the Opternative device operates in a manner that replaces, in whole or in part, a clinician's judgment in the generation of a lens prescription, it raises new and important questions about safety and effectiveness as compared to previously classified devices.

At least one state has taken notice of this issue and the risks that it presents. Specifically, in February of 2016, the Michigan Department of Licensing and Regulatory Affairs issued a cease and desist order to Opternative based on its issuance of lens prescriptions without performance of subjective refraction by a licensed eye care professional.[23] AOA understands that other states are also looking at this issue. However, this is a matter that falls squarely within the jurisdiction of the FDA, and it needs to be addressed by this agency.

The lack of provider involvement in Opternative's self-administered tests is particularly concerning in that Opternative provides prescriptions for contact lenses. Both FDA and AOA have engaged in efforts to educate the public on the significant risks of purchasing and wearing contact lenses without a proper fitting from an eye care professional.[24] During such a fitting, the eye doctor performs additional tests, often in conjunction with diagnostic pharmaceutical agents, and observes the actual fit of the lens on the eye. Contacts must be fitted to a particular size , series of curves, edge design and lens material based on the oxygen demand of the patient's cornea to ensure that they fit a patient's eye; improperly-fitted contacts can pose significant risks. Without this necessary additional step, users at put at risk for poor fitting lenses, dry eye, and other complications.

For example, a contact lens that does not fully meet all necessary parameters of the patient's specific needs can cause new fragile blood vessels to grow into the cornea, a process known as neovascularization. These vessels can leak and cause corneal disease that is undetectable by the individual wearing the contact lenses. Opternative overlooks these ocular risks by deeming examination of the user by the eye doctor unnecessary in the prescribing of contact lenses. In addition, the lack of meaningful involvement of a treating clinician means that there is no mechanism to report adverse events related to contact lens wear. For many of the

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[22] See Attachment 1, at 2.

[23] Notice of Order to Cease and Desist, In re: Opternative Inc. (Unlicensed), File No. 43-16-140044 (Mich. Dep't of Licensing and Reg. Affairs, Feb. 12, 2016) (Attachment 6).

[24] These efforts have included a joint campaign by FDA, AOA, and the Entertainment Industries Council in 2014. See FDA Teams Up for Novel Campaign on Risks of Decorative Contact Lenses (July 24, 2014), available at http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm402704.htm.

same safety reasons, CDRH has issued warning letters to manufacturers of unapproved contact lenses that are sold directly to individuals without the order of a licensed physician.[25]

III. REQUESTED ACTION

FDA should not permit the continued marketing of the Opternative device until CDRH has reviewed the safety and efficacy issues raised by the device. Because the Opternative device does not fit within the existing classification regulation for a visual acuity chart or any other existing classification regulation for ophthalmic devices, it is necessarily considered a Class III device for which an approved PMA is required. 21 U.S.C. § 360c(f)(1), 360e(a)(2). Marketing of the product is, therefore, unlawful until FDA has approved a PMA or has otherwise allowed the marketing of the device.

In the alternative, CDRH could permit Opternative to file a de novo request for classification of the device. Id. § 360c(f)(2)(A)(ii). Once again, however, continued marketing of the device should not be permitted unless the agency grants a de novo request. If Opternative does file a de novo request, CDRH should classify the device into class II or class III. In general, a lower classification would be appropriate only if the general controls of the FDCA—i.e., adulteration, misbranding, registration, banned devices, notification and other remedies, records and reports, and general device provisions—were sufficient to provide reasonable assurance of the safety and effectiveness of the device. Id. § 360c(a)(1)(A)(i). Here, as the foregoing discussion demonstrates, there is, at the very minimum a need for special controls to address the potential for inaccurate prescriptions and the risks that arise from the lack of examination by an eye doctor. There is also a need to make sure that the labeling of the device can be understood and followed by patients, includes all material facts (See 21 U.S.C. §321(n)), and is not false or misleading in any manner.

In no circumstance should CDRH simply clear a 510(k) premarket notification for the device and thereby find that the device is substantially equivalent to a legally marketed device. That approach is precluded because, as explained above, the device does not have the same technological characteristics as, and raises questions of safety and effectiveness different from, other legally marketed ophthalmic devices. Id. § 360c(i)(1)(A) (prohibiting a finding of substantial equivalence unless "a device being compared to a predicate device . . . has as the same technological characteristics as the predicate device, or . . . has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary . . . , that demonstrates that the device is as safe and effective as a legally marketed device, and . . . does not raise different questions of safety and effectiveness than the predicate device").

At a minimum, CDRH should require that Opternative and every manufacturer of a similar device submit an application that details all of the methods used to generate components of a prescription from vision tests, data validating each method, labeling that provides directions for self-administration of the tests, and data demonstrating the ability of patients to appropriately test themselves when following the directions. An ongoing requirement for review of these devices, even after classification, is particularly important given the complexity and range of methods that are possible for generating the components of a prescription. This is evidenced by the many methods disclosed in Opternative's patent, only some of which appear to be used in the currently marketed device. CDRH's review should also assure that the device is

[25] See, e.g., FDA Warning Letter to Crystal Reflections International, Inc. (Jun. 14, 2007).

contraindicated in patients at risk for any eye condition or general health condition that could be misdiagnosed by the device and that requires treatment other than a lens prescription.

At this point, no 510(k) premarket notification has been cleared, no de novo request has been granted, and no PMA for the Opternative device has been approved. Accordingly, the device is a Class III device that is adulterated and misbranded. It should be taken off the market until CDRH has studied the technology and use of the device, its safety and effectiveness, and the claims that are being made for the device in labeling. This action should be taken promptly.

If you have any questions regarding the scientific and regulatory issues raised by the Opternative device, as stated through this complaint, please contact me at president@aoa.org. In addition, clinical questions may be directed to the AOA Chief Public Health Officer, Michael Dueñas, O.D., FNAP, at mduenas@aoa.org For now, thank you for your consideration of this matter.

Sincerely,

Steven A. Loomis, O.D.
President

cc: Malvina Eydelman, MD
Director, Division of Ophthalmic and Ear, Nose, and Throat Devices
CDRH Office of Device Evaluation

Bradley Cunningham, MS
Chief, Diagnostic and Surgical Devices Branch
Division of Ophthalmic and Ear, Nose, and Throat Devices
CDRH Office of Device Evaluation

List of Attachments

Attachment 1 Content of www.Opternative.com (accessed Mar. 21, 2016)

Attachment 2 U.S. Patent No. 9,237,842 (filed Mar. 3, 2014)

Attachment 3 Screen Shots Taken During Use of the Opternative Device (accessed Mar. 1, 2016)

Attachment 4 2015 Establishment Registration and Device Listing for Opternative, Inc. (accessed Feb. 23, 2016)

Attachment 5 Appendix of Technical Considerations Related to Safety and Effectiveness of the Opternative Device

Attachment 6 Notice of Order to Cease and Desist, In re: Opternative Inc. (Unlicensed), File No. 43-16-140044 (Mich. Dep't of Licensing and Reg. Affairs, Feb. 12, 2016)