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VIA ELECTRONIC SUBMISSION
CDRHDeviceAllegations@fda.hhs.gov

Center for Devices and Radiological Health
Office of the Center Director
U.S. Food and Drug Administration
10903 New Hampshire Avenue, WO66-5431
Silver Spring, MD 20993-0002

**Re: Formal Complaint Regarding the Eyebot Vision Testing
Device Manufactured by 123 SEE, Inc. — Concerns
Regarding Regulatory Classification, Unsubstantiated
Marketing Claims, Patient Safety, and Software Validation**

Dear Sir or Madam:

The American Optometric Association (“AOA”) respectfully submits this formal complaint to the Center for Devices and Radiological Health (“CDRH”) of the U.S. Food and Drug Administration (“FDA”) concerning the Eyebot vision testing device manufactured and marketed by 123 SEE, Inc. (doing business as “Eyebot”). This complaint is filed following a productive meeting between AOA representatives and FDA officials and is intended to bring to the Agency’s attention a series of regulatory, safety and marketing concerns that, in AOA’s view, warrant immediate investigation and enforcement action.

The AOA represents over 50,000 doctors of optometry, optometry students and paraoptometric assistants in the United States.¹ The AOA is committed to advocating for the highest standards of patient safety and ensuring that medical devices used in eye care comply fully with applicable federal laws and regulations.

I. BACKGROUND

Eyebot is a self-serve, automated vision testing kiosk currently deployed in retail locations including Walmart Vision Centers, Sam’s Club Optical Centers, and shopping malls across multiple states. Notably, while Eyebot claims to be addressing patient access issues, their kiosks have been deployed in counties that already have doctors of optometry available for full comprehensive care.

¹ See American Optometric Association, “AOA Addresses Eyebot Technology,” available at <https://www.aoa.org/news/advocacy/patient-protection/aoa-addresses-eyebot-technology>.

The Eyebot device is manufactured by 123 SEE, Inc., a company founded in Boston in 2021.² Eyebot kiosks purport to provide consumers with a vision test that results in an eyeglass prescription, which is reviewed by a licensed remote doctor and typically made available within 24 hours.³

According to information reviewed by the AOA, the Eyebot system is comprised of three Class I medical devices registered with the FDA:

1. **Digital Visual Acuity Chart** — Regulation Number 886.1150: A device that is a chart with block letters or other symbols in graduated sizes, intended to test visual acuity.⁴
2. **Lens Measuring Instrument (Lensometer)** — Regulation Number 886.1425: An AC-powered device intended to measure the power of lenses, prisms and their centers.⁵
3. **Ophthalmic Refractometer** — Regulation Number 886.1760: An automatic AC-powered device that consists of a fixation system, a measurement and recording system, and an alignment system intended to measure the refractive power of the eye by measuring light reflexes from the retina.⁶

123 SEE has combined all three Class I devices into a single automated combination device operated by consumers without the assistance of a trained eye care professional. The AOA has identified substantial concerns regarding this combination device, as detailed below.

II. REGULATORY CLASSIFICATION CONCERNS

A. The Combination Device’s Intended Use Differs from the Individual Predicate Devices

Each of the three Class I devices that comprise the Eyebot system was classified and exempted from premarket notification based on its individual intended use as described in Title 21 of the Code of Federal Regulations. These devices were each designed to be used by or under the supervision of a trained eye care professional in a clinical setting. However, Eyebot has combined all three devices into a single, self-administered consumer product deployed in retail environments without direct clinical supervision. This fundamentally alters the intended use of each component device.

² See Eyebot, “Our Technology,” available at <https://www.eyebot.co/our-technology>; see also Heather Landi, “Eyebot Wants to Make Vision Care More Accessible Through AI-Powered Kiosks. It Just Nabbed \$6M to Expand,” *Fierce Healthcare* (June 6, 2024).

³ See Eyebot, <https://www.eyebot.co> (stating “Eyebot solutions are easy to use for adults aged 18-64” and describing over 300 sessions per day); see also “Automated Vision-Testing Kiosks Face Concerns Amid National Expansion,” *Glance* (Feb. 3, 2026).

⁴ 21 C.F.R. § 886.1150 (defining “Visual acuity chart” as “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”).

⁵ 21 C.F.R. § 886.1425 (defining “Lens measuring instrument” as “an AC-powered device intended to measure the power of lenses, prisms, and their centers (e.g., lensometer”).

⁶ 21 C.F.R. § 886.1760 (defining “Ophthalmic refractometer” as “an automatic AC-powered device that consists of a fixation system, a measurement and recording system, and an alignment system intended to measure the refractive power of the eye by measuring light reflexes from the retina”).

Furthermore, Eyebot’s marketing materials and public statements indicate that the combination device is intended not merely to perform the discrete functions of each component device, but rather to serve as a comprehensive vision testing system capable of generating eyeglass prescriptions and screening for eye diseases.⁷ This expanded intended use goes far beyond what any of the three individual Class I devices were designed, classified or authorized to do.

B. Reclassification as a Class II Device May Be Required

The AOA respectfully submits that the combination of three Class I devices into a single automated product—with a materially different intended use, in a non-clinical setting and without professional supervision—may constitute a new device that falls outside the scope of the existing Class I exemptions.⁸ The combination may introduce risks not contemplated when each device was individually classified, including risks arising from the integration of software, the elimination of professional oversight, and the reliance on consumer self-administration.⁹

The AOA requests that the FDA evaluate whether the Eyebot combination device should be reclassified as a Class II medical device requiring a 510(k) premarket notification submission, or whether other regulatory action is appropriate.

Additionally, the AOA notes that 123 SEE does not appear to have registered the Eyebot combination product either as a new device or as a kit, as would be required under applicable FDA regulations.

III. UNSUBSTANTIATED AND MISLEADING MARKETING CLAIMS

A. Disease Screening Claims

Eyebot has made numerous public claims regarding the diagnostic capabilities of its device that appear to exceed the capabilities of the underlying Class I devices. On its website and in marketing materials, Eyebot has stated, among other things, that: (i) “a licensed eye doctor screens your results for over 30 eye-related diseases, including cataracts”¹⁰; (ii) “Eyebot vision screenings allow our tele-doctors to craft an eyeglass prescription and assess your risk for certain eye diseases”¹¹; and (iii) “Eyebot is constantly improving to screen for a wider range of diseases.”¹²

⁷ See Eyebot, “Our Technology,” <https://www.eyebot.co/our-technology>; see also AOA Eyebot Analysis Presentation, Slide 4 (“Concern that the three predicate devices Eyebot has registered with FDA do not actually have the capability to act as a screening for disease”).

⁸ See Eyebot, “Our Technology,” <https://www.eyebot.co/our-technology>; see also AOA Eyebot Analysis Presentation, Slide 4 (“Concern that the three predicate devices Eyebot has registered with FDA do not actually have the capability to act as a screening for disease”).

¹⁰ Eyebot website, available at <https://www.eyebot.co/our-technology>; see also AOA Eyebot Analysis Presentation, Slide 4 (quoting Eyebot: “a licensed eye doctor screens your results for over 30 eye-related diseases, including cataracts”).

¹¹ AOA Eyebot Analysis Presentation, Slide 4 (quoting Eyebot: “Eyebot vision screenings allow our tele-doctors to craft an eyeglass prescription and assess your risk for certain eye diseases”).

¹² Id. (quoting Eyebot: “Eyebot is constantly improving to screen for a wider range of diseases”).

It is well established that visual acuity tests can assist in the detection of cataracts, and refractometers can help identify myopia, hyperopia and astigmatism. The third device, a lens-measuring instrument, measures the power of lenses a patient already has in their existing eyeglasses. It is not clear whether any of these three devices—either individually or in combination—provide sufficient data to enable an eye care professional to determine the presence of “30 eye-related diseases.” The AOA requests that the FDA investigate whether 123 SEE has provided documentation substantiating the claim that a doctor could determine the presence of 30 or more eye-related diseases using the Eyebot combination device, and whether such claims constitute misbranding under the Federal Food, Drug, and Cosmetic Act.¹³

Notably, the President of the Pennsylvania Optometric Association has publicly emphasized that Eyebot kiosks test only the refraction of the eye and do not perform any sort of examination for eye disease.¹⁴ The AOA has further noted that individuals who use the Eyebot kiosk may incorrectly assume they are receiving the full breadth of services provided during an in-person eye examination and may forgo necessary follow-up testing for conditions such as glaucoma, cataracts and other diseases.¹⁵

B. Variances from Predicate Devices

The AOA has identified significant variances between the Eyebot device and the predicate devices upon which its Class I registration appears to be based. Notably, the Visibly Digital Acuity Product (“VDAP”), a comparable remote visual acuity testing device, received FDA 510(k) clearance as a Class II device (K220090)¹⁶ with specific limitations: it is cleared for use only by adults ages 22 to 40,¹⁷ it must be administered as a self-guided test in conjunction with a touchscreen mobile device and internet-connected computer, and the FDA explicitly stated that the VDAP “does not provide screening or diagnosis of eye health or other disease and does not replace an eye health exam with a licensed provider.”¹⁸

By contrast, Eyebot markets its device for use by adults ages 18 to 64¹⁹—a significantly broader age range than the cleared VDAP predicate device. Moreover, unlike the VDAP, Eyebot affirmatively claims disease-screening capabilities. These material differences raise serious questions about whether the Eyebot device can properly rely on Class I exemptions and whether it should be subject to the same or more rigorous premarket review as the VDAP.

C. Marketing to Children and Older Adults

¹³ See 21 U.S.C. § 352 (misbranding provisions of the Federal Food, Drug, and Cosmetic Act).

¹⁴ Dr. Erin Draper, President, Pennsylvania Optometric Association, as quoted in Kent Jackson, “A Robot Helped Prescribe My Eyeglasses,” *Standard-Speaker* (Feb. 13, 2026) (emphasizing that Eyebot kiosks only test refraction and do not examine for any eye diseases).

¹⁵ See AOA, “AOA Addresses Eyebot Technology,” *supra* note 1 (noting that patients “may not see the need for testing for glaucoma, cataracts or other common vision-related diagnoses” after receiving an Eyebot prescription).

¹⁶ FDA, 510(k) Summary, K220090 (Aug. 12, 2022) (clearing the Visibly Digital Acuity Product), available at https://www.accessdata.fda.gov/cdrh_docs/pdf22/K220090.pdf.

¹⁷ See “Visibly Becomes First FDA-Cleared Online Vision Test in the United States,” *PR Newswire* (Aug. 16, 2022) (“The test is designed to be used by adults between the ages 22 to 40.”); see also “Online Visual Acuity Test Gains FDA Clearance,” *Optometry Times* (Nov. 27, 2025).

¹⁸ FDA, 510(k) Summary, K220090, *supra* note 24 (stating the VDAP “does not provide screening or diagnosis of eye health or other disease and does not replace an eye health exam with a licensed provider”).

¹⁹ Eyebot, <https://www.eyebot.co> (“Eyebot solutions are easy to use for adults aged 18-64”).

Although Eyebot’s website states that its solutions are for adults ages 18 to 64, a review of Eyebot’s online content—including its blog²⁰ and resources pages²¹—reveals extensive discussion of children’s vision, including information about how often children should have their vision checked. This content appears designed to imply that the Eyebot device is suitable for use with pediatric patients, despite the fact that: (i) Eyebot’s own stated age range begins at 18; (ii) the comparable VDAC predicate device is approved only for ages 22 to 40; and (iii) vision testing in children requires specialized clinical expertise and instrumentation that an automated kiosk cannot replicate.

The potential for consumers—particularly parents—to be misled into believing that a 90-second automated kiosk test is an adequate substitute for a comprehensive pediatric eye examination poses a significant risk to children’s eye health. Children are at particular risk for undetected vision disorders that require timely professional diagnosis and treatment.²² Similarly, Eyebot’s extension of its stated age range to 64 years raises concerns, as older adults are at significantly increased risk for conditions such as glaucoma, macular degeneration, cataracts, and diabetic eye disease—conditions that require a comprehensive eye examination for detection and cannot be diagnosed through the limited testing offered by an automated kiosk.²³

IV. PATIENT SAFETY CONCERNS

A. Accuracy of Prescriptions

The AOA has received reports raising concerns about the accuracy of prescriptions generated through the Eyebot system. These reports include instances of a single user receiving three different prescriptions after using the system three separate times, as well as users reporting that Eyebot-generated prescriptions were significantly stronger than prescriptions provided through comprehensive in-person examinations by licensed eye care professionals. These accuracy concerns raise questions about the reliability and reproducibility of the device’s measurements.

B. Additional Risks Introduced by the Combination Device

The AOA is concerned that combining three Class I devices into a single automated system introduces additional risks that were not present when each device was used separately in a clinical setting under professional supervision. These risks include, but are not limited to:

- a. The risk of inaccurate measurements due to improper patient positioning or other user errors that would ordinarily be corrected by a trained professional;²⁴

²⁰ Eyebot, <https://www.eyebot.co/resources/?cat=blog> (Resource/Blog page)

²¹ Eyebot, <https://www.eyebot.co/resources/how-often-should-you-get-your-vision-checked> (Blog)

²² See American Optometric Association, “School-Aged Vision: 6 to 18 Years of Age,” available at <https://www.aoa.org/healthy-eyes/eye-health-for-life/school-aged-vision> (explaining that undetected vision problems can impair learning and mimic ADHD symptoms in children).

²³ See National Eye Institute, “Get a Dilated Eye Exam,” <https://www.nei.nih.gov/learn-about-eye-health/healthy-vision/get-dilated-eye-exam> (recommending comprehensive dilated eye exams for adults over age 60 due to elevated risk of glaucoma, cataracts, macular degeneration, and diabetic eye disease).

²⁴ See 21 C.F.R. §§ 886.1150(a), 886.1425(a), 886.1760(a) (each defining intended use in the context of clinical measurements performed by or for a healthcare professional).

- b. The risk that consumers will rely on the Eyebot test as a substitute for a comprehensive eye examination, resulting in the failure to detect serious eye diseases and other health conditions;
- c. The risk that inaccurate prescriptions will lead to vision impairment, headaches, eyestrain and other adverse effects; and
- d. The risk arising from the integration and interaction of multiple device software systems that have not been independently validated by the FDA.

C. Elimination of Professional Supervision

Each of the three individual Class I devices that comprise the Eyebot system was designed for use by or under the supervision of a trained eye care professional. By deploying these devices in an automated, consumer-operated kiosk, Eyebot has eliminated the professional oversight that is integral to the safe and effective use of these devices. Accordingly, the AOA requests that the FDA evaluate whether the elimination of a trained professional when using these devices introduces additional risks that were not present when each device was used separately by an eye doctor.

V. SOFTWARE VALIDATION

The Eyebot device is powered by proprietary software that integrates the outputs of three separate medical devices, processes the resulting data, and generates recommendations for eyeglass prescriptions. The AOA is not aware of any publicly available documentation indicating that 123 SEE has provided the FDA with validation of the software that powers the combination device. Given the critical role that software plays in the function of the Eyebot system—and the potential for software errors to result in inaccurate prescriptions or missed disease indications—the AOA respectfully requests that the FDA investigate whether adequate software validation has been performed and submitted to the Agency.²⁵

VI. VISUAL ACUITY TEST DESIGN CONCERNS

The AOA has also identified concerns regarding the design of the Eyebot visual acuity test itself. The test reportedly displays four lines of letters, one at a time, with each line's letters appearing progressively smaller. The user is then asked to arrange the displayed letters on a touchscreen. However, the touchscreen provides only the four letters that were displayed, meaning the user cannot guess a completely different letter. This design may artificially inflate visual acuity scores, as the test does not require true letter identification from the full alphabet—which is how standardized visual acuity testing (e.g., ETDRS or Snellen charts) is conducted in clinical practice.²⁶ The limited-choice format may result in a higher proportion of correct responses than the user's actual visual acuity would yield on a standard chart, thereby producing an inaccurate assessment.

VII. REQUESTED ACTIONS

²⁵ See generally FDA, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," (May 11, 2005) (setting forth FDA expectations for software validation in medical devices).

²⁶ See National Research Council, "Visual Acuity Measurement Standard," in Committee on Vision, Working Group 39 (describing standardized visual acuity testing using full-alphabet letter identification with ETDRS and Snellen charts).

In light of the foregoing concerns, the AOA respectfully requests that the FDA take the following actions:

1. **Investigate the Regulatory Classification** of the Eyebot combination device to determine whether the intended use of the combination device matches the intended uses of the individual Class I component devices, and whether the combination device should be reclassified as a Class II device requiring 510(k) premarket notification.
2. **Evaluate the Registration Status** of the Eyebot combination device and determine whether 123 SEE has properly registered the device as a combination product or kit.
3. **Examine Marketing Claims** made by Eyebot, including the claim that the device can screen for “over 30 eye-related diseases” and determine whether such claims are substantiated and whether they constitute misbranding.
4. **Assess the Additional Risks** introduced by combining three Class I devices into a single automated system and by eliminating professional supervision and determine whether such risks require additional regulatory controls.
5. **Investigate Software Validation** to determine whether 123 SEE has provided adequate validation of the software that integrates and powers the combination device.
6. **Review the Accuracy and Reproducibility** of the Eyebot device, including the reported instances of inconsistent prescriptions and prescriptions that deviate significantly from those provided through comprehensive in-person examinations.
7. **Address Marketing to Vulnerable Populations**, including Eyebot’s implied marketing toward children and its expansion of the device’s age range to 64 years, which exceeds the age range of the comparable FDA-cleared VDAP predicate device (22–40 years).

VIII. CONCLUSION

The AOA appreciates the FDA’s attention to this matter and the Agency’s commitment to safeguarding patient health. The concerns outlined in this complaint are significant and, in the AOA’s view, warrant prompt investigation to protect the public from potential harm. The rapid deployment of Eyebot kiosks across multiple states in high-traffic retail locations increases the urgency of the issues raised herein.

The AOA stands ready to provide any additional information or assistance that the FDA may require in connection with its review of these matters. We respectfully request that the FDA keep us informed of any actions taken in response to this complaint.

Thank you for your consideration.

Respectfully submitted,



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