September 30, 2022

Visibly, Inc.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, 23rd Floor
Philadelphia, Pennsylvania 19103

Re: K220090
Trade/Device Name: Visibly Digital Acuity Product
Regulation Number: 21 CFR 886.1150
Regulation Name: Visual Acuity Chart
Regulatory Class: Class I
Product Code: QTO

Dear Janice Hogan:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 12, 2022. Specifically, FDA is updating this SE Letter as an administrative correction because of a typo in the Indications for Use form.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Elvin Ng, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, 240-402-4662, Elvin.Ng@fda.hhs.gov.

Sincerely,

Elvin Y. Ng -S

Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

August 12, 2022

Visibly, Inc.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, 23rd Floor
Philadelphia, Pennsylvania 19103

Re: K220090
Trade/Device Name: Visibly Digital Acuity Product
Regulation Number: 21 CFR 886.1150
Regulation Name: Visual Acuity Chart
Regulatory Class: Class I
Product Code: QTO
Dated: January 11, 2022
Received: January 11, 2022

Dear Janice Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tieuvi H. Nguyen -S

for Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: June 30, 2023
See PRA Statement on last page

510(k) Number *(if known)*

K220090

Device Name

Visibly Digital Acuity Product

Indications for Use *(Describe)*

The Visibly Digital Acuity Product (VDAP) is a web-based, self-guided software application intended for use by adults, ages 22 to 40, who have the capability to perform a self-test at home, to aid in the evaluation of visual acuity with or without correction. The software allows users to view and respond to displayed optotypes and uses the responses to categorize a patient's visual acuity into one of two categories, with an individual output for each eye:

- TRUE - visual acuity that is consistent with normal vision
- FALSE - visual acuity that is not consistent with normal vision

The Visibly Digital Acuity Product recommendations are intended to be supportive recommendations that will be used by an eye care provider, along with the patient's medical history and profile, prior corrective eyewear prescriptions, and subjective vision data. The Visibly Digital Acuity Product does not provide screening or diagnosis of eye health or other disease, nor is it intended to replace an in-person eye exam.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY
Visibly, Inc.'s Visibly Digital Acuity Product
K220090

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Visibly, Inc.
207 E Ohio Street, #233
Chicago, IL 60611
Phone: 217-971-4852
Contact Person: Paul Foley CFO/COO

Date Prepared: August 11, 2022

Name of Device

Visibly Digital Acuity Product

Classification Name

Visual Acuity Chart (21 CFR 886.1150, Class I, Product Code QTO)

Predicate Devices

Predicate Device:

Vimetrics, LLC Central Vision Analyzer (CVA-1000)

Reference Devices:

SoloHealth, Inc. SoloHealth Station (K113402)

Vital Art and Science, Inc. MyVisionTrack Model 005 (K143211)

Intended Use / Indications for Use

The Visibly Digital Acuity Product (VDAP) is a web-based, self-guided software application intended for use by adults, ages 22 to 40, who have the capability to perform a self-test at home, to aid in the evaluation of visual acuity with or without correction. The software allows users to view and respond to displayed optotypes and uses the responses to categorize a patient's visual acuity into one of two categories, with an individual output for each eye:

- TRUE - visual acuity that is consistent with normal vision
- FALSE - visual acuity that is not consistent with normal vision

The Visibly Digital Acuity Product recommendations are intended to be supportive recommendations that will be used by an eye care provider, along with the patient's medical history and profile, prior corrective eyewear prescriptions, and subjective vision data. The Visibly Digital Acuity Product does not provide screening or diagnosis of eye health or other disease, nor is it intended to replace an in-person eye exam.

Technological Characteristics

The Visibly Digital Acuity Product is a web-based, software application intended for use by adults, at home, to aid in the evaluation of visual acuity with or without correction. The standalone software application allows the user to interface with the software via a web browser on two internet-enabled devices:

- A computer screen (the Display) which displays optotypes.
- A touchscreen mobile device (the Remote) which operates as a remote control and interface for the user to respond to prompts related to the optotypes appearing on the Display while standing 10 feet away.

The software allows users to view and respond to displayed optotypes and uses the responses to categorize a user's vision acuity into one of two buckets: (1) TRUE - visual acuity that is consistent with normal vision (2) FALSE - visual acuity that is not consistent with normal vision.

A table comparing the key features of the subject, predicate, and reference devices is provided below.

	Visibly Digital Acuity Product (subject)	**Vimetrics Central Vision Analyzer 1000 (CVA-1000) (predicate)**	**SoloHealth Station (reference)**	**MyVisionTrack Model 0005 (reference)**
510(k)	K220090	K100095	K113402	K143211
Product Code	QTO	HOX, Chart, Visual Acuity	DXN, Automated Blood Pressure Monitor HOX, Chart, Visual Acuity	HOQ, Amsler grid
Indications for Use	The Visibly Digital Acuity Product (VDAP) is a web-based, self-guided software application intended for use by adults, ages 22 to 40, who have the capability to perform a self-test at home, to aid in the evaluation of visual acuity with or without correction. The software allows users to view and respond to	The CVA-1000 is intended for use under the direct supervision of an ophthalmologist or optometrist in the measurement of vision at fixation in one or both eyes, with or without optical correction.	The SoloHealth Station is intended to be used by the general public so that a user can measure his/her own blood pressure and pulse rate and his/her own weight. Additionally, the SoloHealth Station is intended to screen adults for clarity of central vision. SoloHealth Station does not provide a general	The myVisionTrack® Model 0005 is intended for the detection and characterization of central 3 degrees metamorphopsia (visual distortion) in patients with maculopathy, including age-related macular degeneration and diabetic retinopathy, and as an aid in monitoring

	Visibly Digital Acuity Product (**subject)**	**Vimetrics Central Vision Analyzer 1000 (CVA-1000) (predicate)**	**SoloHealth Station (reference)**	**MyVisionTrack Model 0005 (reference)**
	displayed optotypes and uses the responses to categorize a patient's visual acuity into one of two categories, with an individual output for each eye: ● TRUE - visual acuity that is consistent with normal vision ● FALSE - visual acuity that is not consistent with normal vision The Visibly Digital Acuity Product recommendations are intended to be supportive recommendations that will be used by an eye care provider, along with the patient's medical history and profile, prior corrective eyewear prescriptions, and subjective vision data. The Visibly Digital Acuity Product does not provide screening or diagnosis of eye health or other disease, nor is it intended to replace an in-person eye exam.		screening of visual function and does not provide a diagnosis of eye health or other disease. The SoloHealth Station only screens clarity of central vision. Users should consult their personal physicians if they have concerns regarding their eyesight.	progression of disease factors causing metamorphopsia. It is intended to be used by patients who have the capability to regularly perform a simple self-test at home. The myVisionTrack® Model 0005 is not intended to diagnose; diagnosis is the responsibility of the prescribing eye-care professional.

	Visibly Digital Acuity Product (**subject)**	**Vimetrics Central Vision Analyzer 1000 (CVA-1000) (predicate)**	**SoloHealth Station (reference)**	**MyVisionTrack Model 0005 (reference)**
Intended Population	Adults, ages 22 to 40	General Public	General Public	Patients at high risk or already diagnosed with maculopathy
Prescription or OTC	OTC	Prescription	OTC	Prescription home use by patients
Device Type	Web-based software application	Device with electronic display	Device with electronic display	Downloadable application to cell phone or tablet
Hardware Platform	Display: Computer, laptop or tablet Remote: Touchscreen smartphone or mobile device	Display: Computer, 2 LCD computer monitors, keyboard, mouse	Display: LCD computer monitor, Interactive Central Vision Panel	Display: User supplied cell phone or tablet
Software Design	Interactive software platform with audio and visual prompts	Interactive software platform with audio and visual prompts. It has two panels: Interactive Central Vision Panel and Chart Panel	Interactive software platform with audio and visual prompts	Interactive software platform with visual prompts
Target Presentation	Landolt C optotypes with crowding bars, facing 4 different directions (openings at 180, 270, 0, and 90 degrees) Optotypes are presented singly	Multiple and Individual optotypes (depending on the panel selected)	Multiple optotypes as well as sentences and paragraphs	Distorted and undistorted shapes
How/Where Used	At home	Clinical environments	Non-clinical environments	At home
Test Administration	Self-administration	Setup and Testing Method is selected by HCP	Self-administration	Self-administration

	Visibly Digital Acuity Product (subject)	**Vimetrics Central Vision Analyzer 1000 (CVA-1000) (predicate)**	**SoloHealth Station (reference)**	**MyVisionTrack Model 0005 (reference)**
		Testing process is completed via self-administration		
Test Procedure Summary	Based on optotypes presented on the Display, the user will select what object they see on their Remote. The following outputs are generated for Eye Care Provider (ECP) review: (1) user-inputted data confirmed during Qualification; (2) Visual Acuity output by eye classifying the individual eye's vision into one of the following buckets: ● TRUE - visual acuity that is consistent with normal vision ● FALSE - visual acuity that is not consistent with normal vision	Chart Panel: A monitor, viewed by the patient, presents traditional symbol charts with progressive 0.1 logMAR gradations of symbol size, each of which may be presented in the following Michelson contrasts of black letters presented against a white background in a range of progressively reduced contrasts. The examiner may view on the physician monitor what is presented to the patient on the patient monitor so he can mark the letters that are correctly identified, allowing either line-by-line or letter-by-letter scoring. The total letters read correctly are recorded as well as the smallest line read correctly in which the traditional method of scoring is utilized. Interactive Central Vision Panel: A monitor is viewed by	Near distance screening is simulated at 17 inches through a series of prompts on the computer monitor where patients are asked to view the clarity of sentences and letters at different sizes. Far distance screening is simulated at 11 feet through a view finder on the device. Patients are asked to determine the clarity of a set of letters.	The myVisionTrack® Model 0005 implements a shape discrimination hyperacuity (SDH) vision test. The distorted shape is created by modulating the radius of the circle with a sinusoid. The user is shown four circles and asked to identify the distorted circle.

	Visibly Digital Acuity Product (subject)	Vimetrics Central Vision Analyzer 1000 (CVA-1000) (predicate)	SoloHealth Station (reference)	MyVisionTrack Model 0005 (reference)
		the patient in which automated measurements are conducted by an interactive computer program at logMAR 0.05 gradations of symbol size. The patient sits in a chair in the darkened examination room with or without optical correction (spectacles, contact lenses, or trial lenses) and with one eye or both eyes exposed, he/she views in a mirror at the end of the room an LCD monitor (patient monitor) mounted on the wall next to the examiner's desk (total distance entered into the computer program at the time of installation). The examiner selects the method of operation and contrasts to be tested by keyboard and mouse interaction and with information presented on the physician's working monitor.		

Performance Data

The following testing is provided to support the safety and performance of the VDAP:

- Luminance Testing was completed to demonstrate that the luminance of the Display hardware is above the minimum threshold for luminance (80 cd/m^2) in accordance with: (1) ANSI Z80.21-2010(R2015). American National Standard for Ophthalmics - Instruments - General-Purpose Clinical Visual Acuity Charts; (2) ISO 8596:2017. Ophthalmic optics - Visual acuity testing - Standard and clinical optotypes and their presentation and (3) International Council of Ophthalmology (1984) Visual Acuity Measurement Standard.

- Optotype Sizing Testing was conducted to validate each optotype size rendered during the VDAP test. For each of the 22 optotypes presented by the visual acuity test, the arc length of optotype gap and the optotype diameter were measured using manufacturer-calibrated Mitutoyo Digital Calipers. All measurements of arc length and optotype diameter were ±5% of the pre-specified size equivalent for each LogMar Size.

- Human Factors testing to confirm that the VDAP can be used safely and effectively by the intended users in the intended use environment – i.e., adults aged 22 to 40 years old in a home environment (n=18). This testing established that the overall residual risk of use errors with the VDAP have been mitigated to an acceptable level. Therefore, VDAP can be used without use errors or problems that could result in an inaccurate visual acuity assessment.

- The controlling software for the VDAP presents a “moderate” level of concern as defined in FDA’s “Guidance for the Content of Premarket Submission for Software Contained in Medical Devices” (May 2005). The appropriate supportive software documentation was provided, including a hazard analysis. Verification and validation activities demonstrated that VDAP functioned as intended. In addition, since the VDAP is sent to a medical device data system (MDDS) that is necessary for viewing by clinicians, Visibly provided software documentation consistent with a minor level of concern for the MDDS per the FDA Guidance "Multiple Function Device Products: Policy and Considerations" (July 2020).

- Potential cybersecurity risks were addressed by providing the documentation requested in the FDA Guidance “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices” (October 2014). The software mitigates or prevents the unauthorized access, modification, misuse and unauthorized use of information that is stored, accessed or transferred.

A prospective, multi-center clinical study was also completed (n=329) to evaluate the safety and effectiveness of the VDAP compared to an ETDRS Visual Acuity (VA) Lane Test. This study evaluated the agreement of the VDAP with the ETDRS VA Lane Test as well as the reproducibility of the VDAP. The primary agreement endpoints were the PPV, defined as the proportion of study eyes with VA of 20/25 or better for which ETDRS VA was also 20/25 or better, and the NPV, defined as the proportion of study eyes with VDAP VA worse than 20/25 for which ETDRS VA was also worse than 20/25. Supportive analyses included a subgroup analysis for performance stratified by the actual, measured viewing distance from which the subjects took the VDAP test.

Selection of the study eye occurred after subjects exited the study following the completion of VDAP and ETDRS assessments of each eye. The study eye was selected based upon the

subject's first VDAP VA assessment. If one of the subject's eyes had "20/25 of Better" VDAP VA and the other eye had "Worse than 20/25" VDAP VA, the eye with the "Worse than 20/25" was selected as the study eye. If both eyes had the same VDAP VA, the study eye was selected randomly.

The observed PPV, NPV, sensitivity, and specificity for study eyes were as follows: (97.3%, 95% CI: 95.2% - 99.4%), (48.1%, 95% CI: 38.6% - 57.6%), 79.7% (95% CI: 74.9% - 84.5%) and 89.5% (95% CI: 81.5% - 97.4%). The observed PPV, NPV, sensitivity, and specificity for non-study eyes were as follows: (94.5%, 95% CI: 91.9% - 97.2%), (50.9%, 95% CI: 37.5% - 64.4%), 90.9% (95% CI: 87.6% - 94.2%) and 64.3% (95% CI: 49.8% - 78.8%).

Observed agreement performance in sensitivity and specificity diverged between the Study Eye and Non-Study Eye cohorts due to the study eye selection methodology discussed above. As a result, a pooled analysis combining Study Eye and Non-Study Eyes was completed.
The observed PPV, NPV, sensitivity, and specificity for the pooled Study Eye and Non-Study Eye cohort were as follows: (95.8%, 95% CI: 93.6% - 97.6%), (49.1%, 95% CI: 40.0% - 58.1%), 85.5% (95% CI: 81.9% - 88.9%) and 78.8% (95% CI: 69.1% - 87.6%).

PPV and NPV in the pooled cohort are similar to what was observed in Study Eye and Non-Study Eye Cohorts. Sensitivity and Specificity for the pooled cohort reflect true device performance for these metrics as they are not impacted by the study eye selection methodology in the way the Study Eye and Non-Study Eye Cohorts were.
The secondary agreement endpoint was subject level agreement, defined as the proportion of subjects with matching VDAP and ETDRS classifications (20/25 or Better vs. Worse than 20/25) for both eyes (study eye and non-study eye). The secondary reproducibility endpoint was subject level reproducibility, defined as the proportion of subjects with matching VDAP VA Classifications for the two VDAP tests for both eyes.

The subject level agreement was as follows: 75.9% (95% CI: 71.3% - 80.5%). The subject level reproducibility was as follows: 82.8% (95% CI: 78.7% - 86.9%).

The primary reproducibility endpoint was the proportion of study eyes with matching VDAP VA classifications for the two VDAP tests. The observed reproducibility for Study Eyes (89.3%, 95% CI: 85.9% - 92.6%) was statistically significantly greater than the performance goal of 75% (p-value < 0.0001). There were no safety concerns found with VDAP assessments throughout the study. Furthermore, the reproducibility of the VDAP was confirmed in this study, and the PPV and NPV results of VDAP demonstrate that the selected cut off point of 20/25 Snellen is appropriate. Therefore, the device performance was adequate to support an indication for use as an aid in the assessment of visual acuity.

Conclusion

The VDAP is as safe and effective as the predicate device. The VDAP also shares similar technological characteristics as the reference devices. The VDAP has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the VDAP and its predicate devices raise no new issues of safety or effectiveness. Furthermore, performance data demonstrate that the VDAP is as safe and effective as the predicate device. Therefore, the VDAP is substantially equivalent.