DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 7, 2017

Vital Art and Science Incorporated
Mike Bartlett
President
2725 N. Spring Drive
Richardson, TX 75082

Re: K121738
Trade/Device Name: myVisionTrack™ Model 0003
Regulation Number: 21 CFR 886.1330
Regulation Name: Amsler grid
Regulatory Class: Class I
Product Code: HOQ
Dated: January 15, 2013
Received: January 17, 2013

Dear Mike Bartlett:

This letter corrects our substantially equivalent letter of February 22, 2013

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. 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 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Denise L. Hampton -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Change Control Table, Change History

Change Control Table

Version	Document Author	Document Approver	Date Approved
1.00	Alexander Beylin, Biomedical Engineer, ODE	Name, Title, Office	MM/DD/YYYY

Complete Change Control Table (all versions) retained in SWIFT Docs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K121738

Device Name
myVisionTrackTM Model 0003

Indications for Use *(Describe)*
The myVisionTrackTM is intended for the detection and characterization of central 3 degrees metamorphopsia (visual distortion) in patients with maculopathy, including agerelated macular degeneration and diabetic retinopathy, and as an aid in monitoring 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 myVisionTrackTM is not intended to diagnose; diagnosis is the responsibility of the prescribing eye-care professional.

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.

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FEB 2 2 2013

5. 510(k) Summary (Revised from Original)

Date prepared: May 24, 2012

K Number K121738

Submitter: Vital Art and Science Incorporated
2725 N. Spring Drive
Richardson, TX 75082-4233

Contact Person: Mike Bartlett
President, Vital Art and Science Incorporated
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Name of the Device and Classification

Type of 510(k) Submission:	Traditional
Trade Name:	myVisionTrack™ Model 0003
Common Name:	Home vision function monitor
Reason for Premarket Notification:	New Device
Regulation Number:	21 CFR 886.1605
Regulation Name:	Perimeter, Automatic, AC-Powered
Regulatory Class:	Class I
Product Code:	HPT

Predicate Devices:

The Vital Art and Science Incorporated myVisionTrack™ Model 0003 (mVT™) is substantially equivalent to the following combination of predicate medical devices:

- ForeseeHome supplied by Notal Vision; Perimeter, Automatic, AC-Powered, 21 CFR 886.1605; K091579; Product Code: HPT
- PreView PHP™ supplied by Notal Vision; Perimeter, Automatic, AC-Powered, 21 CFR Part 886.1605; K05350; Product Code: HPT
- Amsler Grid, a Class I Exempt Preamendments Medical Device (21 CFR 886.1330); Product Code: HOQ

K121738

Brief Device Description:

The myVisionTrack™ is a vision function test provided on a commercially available cell phone. The myVisionTrack™ implements a shape discrimination hyperacuity (SDH) vision test which allows patients to perform their own vision test at home. This enables regular monitoring of disease progression, and for timely detection of significant changes in vision function. If a significant worsening of vision function is detected the physician will be notified and provided access to the vision self-test results so that they can decide whether the patient needs to be seen sooner than their next already scheduled appointment.

Indications for Use:

The myVisionTrack™ 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 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™ is not intended to diagnose; diagnosis is the responsibility of the prescribing eye-care professional.

Indications for Use as compared to the Predicate Device:

myVisionTrack™ and the three predicate devices provide a method for a user to self-test their own vision function. All are used to detect significant changes in vision, which indicate disease progression.

The Amsler Grid, in various paper chart forms, is the most commonly prescribed method for home vision monitoring today. Studies have shown that most patients cannot use it effectively for a number of reasons, including the requirement for the user to remember previous results and to determine for themselves if a significant change has occurred.

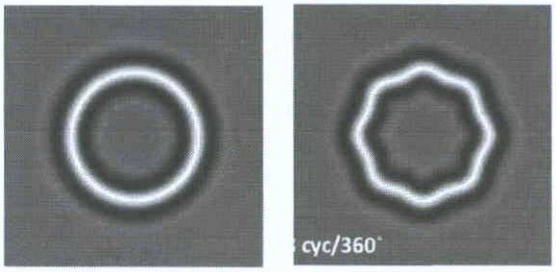
myVisionTrack™ and the two devices from Notal Vision are automated devices which present visual test stimuli, collect user responses and compare current results to previous test results to determine if a significant change in vision function has occurred.

All three devices use a "hyperacuity" algorithm that tests the user's ability to detect differences in multiple stimuli. myVisionTrack™ uses a test algorithm that does not require the user to fixate on a single point during the test. Therefore, it is not limited to users who have a stable fixation, which is a requirement of the Notal Vision devices.

The ForeseeHome and PreView PHP™ test the central and paracentral area of the retina whereas myVisionTrack™ tests only the central 3 degrees of the retina which is a smaller area. The predicate devices are intended for users diagnosed with age-related macular degeneration (AMD) whereas myVisionTrack™ is intended for users diagnosed with maculopathy, of which AMD and diabetic retinopathy (DR) are the primary diseases.

Principles of Operation:

The test images used by myVisionTrack™ are shown in Figure 5.1 where (a) is an undistorted image and (b) is a distorted image. The distorted version is created by modulating the radius of the circle with a sinusoid.



(a) unmodulated (b) modulated

Fig. 5.1. Patterns in the shape discrimination

In the test the user is shown three circles and asked to identify the distorted circle, as shown in Figure 5.2. The test begins with a large amplitude of distortion and moves quickly through a series of test images where the distortion amplitude is reduced in order to determine the lowest detectable level of distortion.

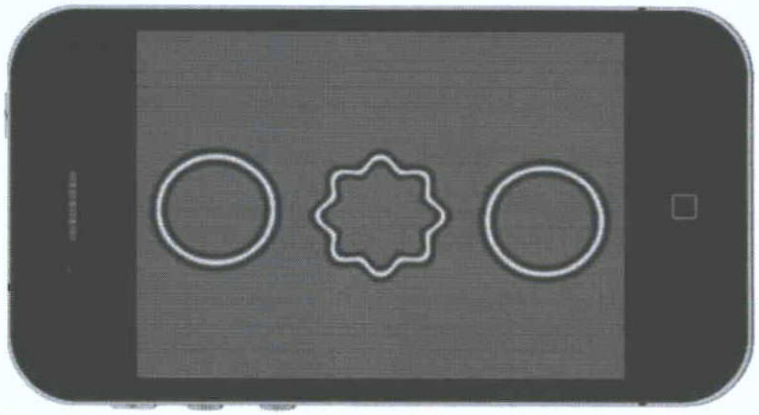


Figure 5.2

Clinical Testing Summary

Numerous published studies have shown that patients with AMD and other forms of maculopathy have significantly poorer results as compared to normal subjects on the shape discrimination test. VAS has performed our own 6-month Clinical Study on the specific shape discrimination hyperacuity test used in myVisionTrack™. This study of diabetic retinopathy (DR) patients did show a significant difference between those patients with mild-to-moderate non-proliferative DR (NPDR) and those with very severe NPDR or proliferative DR (PDR), whereas traditional clinic-based visual acuity and contrast sensitivity tests were not able to detect a significant difference. In this study, where patients were asked to test at least once per week for 6 months, there was an average weekly compliance rate of 84%, and the average number of times the patients performed the test was 1.7. This study verified that patients could and would effectively self-monitor their own vision function at home using myVisionTrack™.

In this 6-month longitudinal study, we collected data on 36 individuals taking weekly measurements for a total of 2338 measurements. Individuals in this study had no significant change of disease condition over the 6-month period based on clinical judgment. Using the 6-month longitudinal study, we found 36 examples where a physician would have been notified according to the 0.2 logMAR notification rule.

Substantial Equivalence Comparison

The substantial equivalence of the myVisionTrack™ to the predicate devices is summarized in Table 5.1 below. Each of these devices provide a vision self-test for the patient.

Item	Function Specification	Amsler Grid Class I Exempt Preamendments Device	Notal Vision, Inc. PreView PHP™ k050350	Notal Vision, Inc. ForeseeHome k091579	VAS myVisionTrack™ Model 0003 (Proposed)
1	Product Code	HOQ	HPT	HPT	HPT
2	Regulation Number	21 CFR 886.1330	21 CFR 886.1605	21 CFR 886.1605	21 CFR 886.1605
3	Indications for Use	Intended to rapidly detect central and paracentral irregularities in the visual field.	The PreView PHP™ is intended for use in the detection and monitoring the progression of Age-related Macular Degeneration (AMD) including, but not limited to, the detection of choroidal neovascularization (CNV).	The ForeseeHome is intended for use in the detection and characterization of central and paracentral metamorphopsia (visual distortion) in patients with age-related macular degeneration as an aid in monitoring progression of disease factors causing metamorphopsia including, but not limited to choroidal neovascularization (CNV). It is intended to be used at home for patients with stable fixation. The ForeseeHome is not intended to diagnose; diagnosis is the responsibility of the prescribing eye-care professional.	The myVisionTrack™ 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 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™ is not intended to diagnose; diagnosis is the responsibility of the prescribing eye-care professional.

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Item	Function Specification	Amsler Grid Class I Exempt Preamendments Device	Notal Vision, Inc. PreView PHP™ k050350	Notal Vision, Inc. ForeseeHome k091579	VAS myVisionTrack™ Model 0003 (Proposed)
4	Target Population	Patients at high risk or already diagnosed with Maculopathy	Patients already diagnosed with age-related macular degeneration	Patients already diagnosed with age-related macular degeneration	Patients already diagnosed with Maculopathy, including age-related macular degeneration and diabetic retinopathy
5	Prescription or OTC	OTC	Prescribed by healthcare professional.	Prescribed by healthcare professional.	Prescribed by healthcare professional.
6	How/Where used	Home use for self-testing by the patient.	Healthcare Clinic	Home use for self-testing by the patient.	Home use for self-testing by the patient.
7	Hardware Platform	Paper chart.	Software Application to be run on a customer supplied off-the-shelf PC.	Dedicated unit with processor, display, mouse and software.	Software Application delivered by the supplier on an off-the-shelf cell phone.
8	Vision Test algorithm used	Patient is instructed to identify and record blur, distorted or missing areas on the chart.	Preferential Hyperacuity Test	Preferential Hyperacuity Test	Shape Discrimination Hyperacuity Test with an adaptive staircase algorithm
9	Fixation Point for the patient during testing?	Yes	Yes	Yes	No. The test employs a visual task involving global visual integration. No fixation is required to perform the test.
10	Data upload capability?	No	Not specified	Yes, through a home phone line.	Yes, through the cell phone connection.

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Standards to which Vital Art and Science Incorporated claims conformance for the myVisionTrack™ Model 0003

1) ISO 13485:2003 / EN ISO 13485:2003 / AC:2009 "Medical devices - Quality management systems - Requirements for regulatory purposes"
2) AAMI / ANSI / ISO 14971:2007/(R)2010, "Medical devices – Application of risk management to medical devices"
3) IEC 60234:2006 Ed. 1.0, "Medical device software – Software life cycle processes"
4) IEC 60601-1:2005 + A1:2012, 'Medical electrical equipment Part 1: General requirements for basic safety and essential performance"
5) IEC 60601-1-2:2007, "Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard Electromagnetic compatibility – Requirements and tests"
6) IEC 60601-1-11:2010, "Medical Electrical Equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment"

Conclusion

In conclusion, the proposed myVisionTrack™ as compared to the already cleared predicate devices has:

- Similar indications for use;
- Similar physical composition, in that all use visual testing software delivered on a validated hardware platform and operating system;
- Similar, but with a vision test algorithm that does not require a patient to focus on a single point constantly during testing;
- A similar method of operation for the patient to perform self-testing at home; and
- Similar central monitoring of patient self-test results, but with a mobile device upload method that does not require the patient to have a home phone or to perform any setup.

Based on our non-clinical and clinical testing of the myVisionTrack™ Model 0003 we have concluded that the myVisionTrack™ Model 0003 is as safe, as effective and performs at least as safely and effectively as the predicate devices.