June 1, 2020

Vasoptic Medical Inc.
Abhishek Rege
President
1215 East Fort Avenue, Suite 304
Baltimore, Maryland 21230

Re: K193319
Trade/Device Name: XyCAM RI, XyCAM RI System, XyCAM Retinal Imaging System
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: November 27, 2019
Received: December 2, 2019

Dear Abhishek Rege:

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,

Elvin Ng
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193319

Device Name
XyCAM™ Retinal Imager - XyCAM RI

Indications for Use *(Describe)*
The XyCAM RI System is intended to capture, store, and display images of dynamic blood flow changes in the human retina, and to provide quantitative outputs of relative blood flow information.

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."

VASOPTIC MEDICAL INC.

510(k) Summary

I. Submitter Details

Submitter Name	Vasoptic Medical Inc.
Submitter Address	1215 East Fort Avenue, Suite 304, Baltimore, MD 21230
Submitter Phone Number	443-961-3591
Primary Contact Person	Abhishek Rege
Primary Contact Email	Abhishek.Rege@vasoptic.com
Date Prepared	November 27, 2019

II. Device Information

Device Name	XyCAM Retinal Imager (XyCAM RI)
Device Identification	Ophthalmic Camera Device
Product Code	HKI
Regulation Number	21 CFR 886.1120
Regulatory Classification	II

III. Predicate Device

Predicate Device	Retinal Functional Imager 3000 (RFI 3000), K080180
Reference Device	Laser Speckle Flowgraphy LSFG-NAVI, K153239

IV. Device Description

The XyCAM™ RI System (or XyCAM RI) is a non-invasive retinal blood flow imaging device. It generates images of one or more regions of the retina by using an imaging technique called Laser Speckle Contrast Imaging (LSCI). This technique utilizes a low-intensity laser beam to illuminate the back of the eye and a high-speed, high-sensitivity camera to acquire a stack of images. The captured image stack is then processed such that the intensity at every image pixel is processed in conjunction with the intensities of other spatio-temporally adjacent pixels to obtain a speckle contrast value at the said pixel, which is indicative of blood flow velocity at the said pixel. Accordingly, the XyCAM RI is able to generate and display a map of Blood Flow Velocity indices within the imaged field of view.

The XyCAM RI System consists of following modules:

- The XyCAM RI contains a module to provide illumination to the back of the eye, various optical components to manipulate light along the illumination and imaging path, a high-speed camera to capture images, visual targets for the imaged subject to fixate his/her gaze on during imaging, and electronic and mechanical components for control and operation.

- System PC contains the XyCAM RI Software. The Operator uses the XyCAM RI System PC keyboard, mouse, and monitor to interact with the XyCAM RI Software, which controls the XyCAM RI operation including management of user and patient information, control of image acquisition, facilitation of image analysis, and generation of imaging results.
- Accessories include an imager station and an external hard drive.
- A pulse oximeter is included as an optional third-party device.

The XyCAM RI Software outputs Blood Flow Velocity indices (arbitrary units) that can be assessed for spatial and temporal trends in user defined regions.

V. Intended Use

The XyCAM RI System is intended to capture, store, and display images of dynamic blood flow changes in the human retina, and to provide quantitative outputs of relative blood flow information.

VI. Comparison of Technological Characteristics with Predicate Device and Reference Predicate

Feature	XyCAM RI System	RFI 3000 (Predicate Device)	LSFG-NAVI (Reference Predicate)
510(K) Number	K19xxxx	K080180	K153239
Product Code	HKI (Primary)	HKI (Primary), HLI (Secondary)	HKI (Primary), HLI (Secondary)
Classification Name	Ophthalmic Camera Device; AC Powered (21 CFR 886.1120)	• Ophthalmic Camera Device; AC Powered (21 CFR 886.1120) • Ophthalmoscope (21 CFR 886.1570)	• Ophthalmic Camera Device; AC Powered (21 CFR 886.1120) • Ophthalmoscope (21 CFR 886.1570)
Class	II	II	II
Method	Imaging is performed using coherent illumination (laser diode).	Imaging is performed using illumination similar to conventional fundus camera.	Image using Diode Laser. A mydriatic agent is not required in a darkroom (displayed on PC monitor).

Feature	XyCAM RI System	RFI 3000 (Predicate Device)	LSFG-NAVI (Reference Predicate)
	A mydriatic agent is not necessary, but may be used if needed.	A mydriatic agent is required.	
Indication for Use	The XyCAM RI system is intended to capture, store and display images of real time dynamic blood flow changes in the human retina, and to provide quantitative outputs of relative blood flow information.	The RFI 3000 is intended to observe, capture, display, and store images of patients' fundus (retina) under mydriatic conditions to aid in diagnosing or monitoring diseases of the eye that may be observed and photographed.	The LSFG-NAVI system is intended to capture and display the blood flow distribution in the human retina in real time, and to monitor the blood flow in retinal vessels for their quantitative evaluation.
Observation System	Software live view	Through eyepiece with reticle or through software live view	Software live view
Imaging Light Source	Near-Infrared (785 ± 10 nm) Laser Diode	Xenon flash lamp 420WS (multi-flash)	Laser Diode (830 nm)
Flash Exposure	Continuous exposure	Automatic, 1 ms per pulse, train of up to 8 pulses, repetition rate 17.5ms.	Continuous exposure
Focusing Light Source	Focusing illumination is the same as imaging illumination	12 V Halogen lamp	LED (940 nm)
Focusing	On-system gaze fixation targets and manual focusing by the operator	Matching two oscillating points	Matching two laser spots
Field Angle	20 to 25 degrees	50, 35, 20 degrees	21 degrees (Horizontal: 21 degrees; Vertical: 12 degrees)

Feature	XyCAM RI System	RFI 3000 (Predicate Device)	LSFG-NAVI (Reference Predicate)
Working Distance	21 mm	40 mm	44 mm
Principle of Blood Flow Measurement	Laser Speckle Contrast Imaging	Frame mapping of xenon flash lamp illumination	Laser Speckle Flowgraphy
Measurement Duration	3 to 6 seconds at 82 Hz	125 ms for data acquisition	30 Hz (typically 4 to 6 seconds)
Measurement Results	Relative value	Given in mm/sec	Relative value
Numerical Data	Blood flow velocity index (BFVi)	Velocity flow rate	Blood flow Index
Graphical Data	Blood Flow Velocity map of retina Blood Flow Velocity map of select regions/vessels Spatial trend of BFVi Temporal trend of BFVi	Path of flow	Perfusion map of retina Time variation of blood flow index
Essential Performance and Electrical Safety Standard	• ANSI/AAMI ES60601-1: 2005 (3rd Edition) • IEC 60601-1-2: 2014 (4th Edition)	• IEC 60601-1: 1st Edition • IEC 60601-1-2: 1st Edition	• IEC 60601-1:2012 • IEC 60601-1-2: 2007
Other Performance Standard	• ANSI Z80.36-2016 • IEC 60825-1: 2007 • ISO 14971: 2007	• ISO 15004-2: 2007 • ISO 10940: 1998 • ANSI RP-27-1-96: 1st Edition • ISO 14971: 2000	• ISO 15004-2:2007 • ISO 10940: 1998 • ISO 60825-1: 2007 • ISO 14971: 2007

While the underlying technologies of XyCAM RI (assessment of blurring in the speckle pattern) and of the predicate (temporal changes in reflectance photographic frames) are different in some aspects, they are substantially equivalent in their approach, the risk profile, and efficacy of producing blood flow information. The measurement output of

the XyCAM RI is a blood flow velocity index (BFVi), a quantitative measure of relative blood flow information, that has been shown to possess repeatability and reproducibility characteristics that are on par or better than the predicate, and conveys substantially equivalent information pertaining to the flow of blood in the human retina. The technological differences do not raise new concerns of safety or effectiveness in the intended use of the XyCAM RI to provide quantitative outputs of relative blood flow information in the human retina. The XyCAM RI has established safety and effectiveness through design verification of the system including software, electromagnetic compatibility, medical product safety, substantial equivalence in output performance, and system validation via clinical testing.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Illumination Classification and Safety
The XyCAM RI is classified as a Class 1 Laser Product and Group 1 Ophthalmic Instrument as defined by IEC 60825:2007 and ANSI Z80.36-2016, respectively. Refer to Section 18.1 for a complete illumination classification and safety analysis.

Electrical Safety and Electromagnetic Compatibility (EMC)
Electrical safety and EMC testing were conducted on the XyCAM RI System. The system complies with the ANSI/AAMI ES60601-1 standard for product safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing
Software verification and validation testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered to be a **"moderate"** level of concern, since a failure or latent flaw in the software could directly result in minor injury to the patient or operator. The XyCAM RI System is designed to provide quantitative outputs of relative blood flow velocity information to clinicians and is not intended to provide any diagnostics or clinical decision support. However, the software is considered to possess a moderate level of concern because a failure or latent flaw could indirectly result in minor injury through the action of a care provider.

Bench Testing
XyCAM RI bench testing involved the use of a calibrated flow pump which provided baseline velocity measurements to analyze against. The results of bench testing demonstrated the XyCAM RI is able to reliably capture retinal blood flow with an intra-session coefficient of variation significantly less than 10%.

Comparative assessment was conducted between the XyCAM RI output of blood flow velocity index (BFVi, in arbitrary units) and RFI 3000 output of blood velocities (in mm/s) when imaging the same tubular blood flow. The results demonstrated substantial

equivalence between the two outputs and consistent repeatable measurements of physiologically relevant blood flow velocities obtained using the XyCAM RI.

Clinical Studies

Clinical testing was conducted to validate that the XyCAM RI is consistently able to generate images of the back of the eye in a diverse range of subjects, and to characterize the repeatability and reproducibility of blood flow measurements when used in the clinic as intended.

Twenty (20) healthy subjects were recruited and imaged, with strict adherence to inclusion and exclusion criteria which were developed to obtain data from a cohort that is representative of the general population. There were 9 male subjects and 11 female subjects imaged, with a combined average age of 46.9 ± 16.6 years. The demographic distribution of subjects is displayed in the table below.

Number of subjects	**Age Range**			
Race	**21 to 40**	**40 to 60**	**> 60**	**Total**
African American	2	4	1	**7**
Caucasian	4	0	5	**9**
Asian	2	2	0	**4**
Total	**8**	**6**	**6**	**20**

To assess measurement errors across imaging sessions and operators, all subjects were divided into three groups: A1 (n=10), A2 (n=5), and A3 (n=5). All subjects in Group A1 was imaged with the field of view centered on the Optic Nerve Head (ONH) and on the macula by one operator. All subjects in Group A2 and A3 were imaged by three operators with the field of view centered on the ONH in Group A2 and centered on the macula in Group A3. To assess repeatability, multiple imaging sessions were conducted by each operator. For each imaging session, five regions of interest (ROIs) were assessed using the XyCAM RI Software, and analyzed across multiple cardiac cycles within an imaging session for intra-session repeatability and across multiple imaging sessions for inter-session repeatability.

Over all regions analyzed, the XyCAM RI's mean intra-session CV was 2.883 ± 1.049% and the mean inter-session CV was 7.069 ± 2.018% in imaging centered around the ONH region and the mean intra-session CV was 2.782 ± 2.044% and the mean inter-session CV was 6.447 ± 3.778% in imaging centered around the macular region.

VIII. Conclusion

The XyCAM RI is substantially equivalent to the predicate device's intended use, functionality and performance. The XyCAM RI successfully passed required verification, validation and product safety testing to demonstrate overall device safety and effectiveness.