DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 12, 2016

Softcare Co., Ltd
% Mr. Takahiro Haruyama
President
Globizz Corporation
1411 W. 190th St., Suite 200
Gardena, CA 90248

Re: K153239
Trade/Device Name: LSFG-NAVI
Regulation Number: 21 CFR 886.1120
Regulation Name: Opthalmic Camera
Regulatory Class: Class II
Product Code: HKI, HLI
Dated: April 8, 2016
Received: April 11, 2016

Dear Mr. Haruyama:

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 Part 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" (21 CFR 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 yours,

Kesia Alexander

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

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)*
K153239

Device Name
Laser Speckle Flowgraphy LSFG-NAVI

Indications for Use *(Describe)*
The Laser Speckle Flowgraphy 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.

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

Submitter's Name:
Software Co., Ltd.
243-5 Yatsunami
Fukutsu City, Fukuoka
811-3201 JAPAN
Phone: +81-940-36-9693

Contact Person:
Noriyoshi Takahashi
Phone: +81-940-36-9693
Email: takahashi@softcare-ltd.co.jp

Official Correspondence:
Takahiro Haruyama
Globizz Corporation
1411 W. 190th St. Suite #200
Gardena, CA 90248

Date of 510(k) summary preparation: November 3, 2015

Trade/Proprietary Name: Laser Speckle Flowgraphy LSFG-NAVI
Common/Usual Name: Ophthalmic Camera Device /Ophthalmoscope
Classification Name:
Camera, Ophthalmic, Ac-powered (21CFR 886.1120, Product Code HKI)
Ophthalmoscope, Ac-powered (21CFR 886.1570, Product Code HLI)

Device Description:
The LSFG-NAVI can visualize and measure the distribution of blood flow in the human retina in a broad area from macular to the optic nerve head. The most useful feature of the instrument is the ability to non-invasively observe varying blood flow synchronized with the heartbeat as a series of 2D blood flow maps.

The LSFG-NAVI consists of following major units:

(1) LSFG-NAVI Camera Unit: including an emitter of a diode laser, retinal camera imaging system, imager, CCD camera (video capturing)
(2) Personal Computer (PC): including LSGF-NAVI System Software (Measurement Software and Analysis Software
(3) 3D-Stage Unit: The LSFG-NAVI Camera Unit is attached to the 3D-Stage unit and a patient places his/her head and face at Chin Rest and Head Rest of the 3D-Stage Unit.
(4) Electronic Unit: including the AC Adapter and Isolation Transformer.

Intended Use:

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.

The LSFG-NAVI Technology:

The LSFG-NAVI is based on image analyses of the so called 'speckle' pattern produced by random laser interference. The system consists of an emitter of a diode laser, retinal camera imaging system, imager, hardware for video capturing and a personal computer (PC). The light from the diode laser is expanded and illuminates the retinal surface with a large spot. The laser is scattered from the moving blood cells flowing in the vessels and the capillary network, and comes back to the image plane of the camera, where the random interference pattern or laser speckles are produced. According to the motion of the blood cells, the structure of the image speckles varies over time, and the rate of variation at that point is proportional to the average flow velocity at the corresponding objective point. The image intensity is captured by a highly sensitive CCD camera and the rate of time variation is calculated at each pixel point. By displaying the results in 2D form, the time varying blood flow maps of the retina become observable as a motion picture.

Non clinical performance data:

LSFG-NAVI has been tested and met the standards for Electrical safety testing of IEC 60601-1, electromagnetic compatibility testing of IEC 60601-1-2, laser safety testing of IEC 60825-1, optical radiation levels of ISO 15004.

The LSFG-NAVI software was also verified and validated according the “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” issued by FDA in 2005. Risk mitigation of LSFG-NAVI software was also carried out based on ISO 14971.

Furthermore, the 3 non-clinical testing were performed to establish its effectiveness and performance,

namely, Validation of blood flow index measurement, validation of time variation of blood flow index measurement, and validation of perfusion map of retina.

The LSFG-NAVI also complies with the radiation safety regulation and the radiation safety report (product report, 21CFR 1002.10) has been submitted and the accession number assigned (#1310447-000).

It is of importance to note that the LSFG-NAVI has not been tested clinically where this statement is included in the User Manual to inform the end user.

Substantial Equivalent:

The Laser Speckle Flowgraphy LSFG-NAVI is considered to be substantially equivalent to the predicate device below:

- Retinal Functional Imager (K062416) - Optical Imaging, Ltd.

The comparison of the technological characteristics between LSFG-NAVI and the Retinal Functional Imager (RFI) - K062416 is summarized below:

Item	LSFG-NAVI	RFI
510(k) number	K153239	K062416
Product Code / Classification	HKI/HLI	HKI/HLI
Classification Name	Ophthalmic Camera Device; AC powered. Ophthalmoscope	Ophthalmic Camera Device; AC powered. Ophthalmoscope
Class	II	II
Method	Image using Diode Laser. A mydriatic agent is not required in a darkroom (displayed on PC monitor).	Similar to conventional fundus camera with eye drop (displayed on PC monitor)

Item	LSFG-NAVI	RFI
Intended Use	The LSFG-NAVI system is 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.	The Retinal Functional Imager is a digital imaging and fundus camera system intended to observe, capture, display, and store images of patients' fundus (retina) under mydriatic conditions and provide information obtained from the images about blood flow (velocity) and path of flow in retinal vessels. The device is indicated for use as an aid in diagnosing or monitoring diseases of the eye that may be observed and photographed.
Modes of operation	Blood flow Index and Perfusion map of retina	Red-free manual multiflash –blood flow velocity and path by flow
Target Population	General	General
Anatomical region	Retina	Retina
Light Source	Laser Diode (830nm)	Halogen lamp 50W
Field angle(degrees)	21	50, 35, 20
Viewing Magnification	1.2X	12.1X, 17.1X, 29.9X
Focusing	Matching two laser spots	Matching two oscillating points
Working distance	44mm	40mm
Record Media	Digital data	Digital data / 35 mm film
Principle of blood flow measurement	Laser Speckle Flowgraphy	Frame Mapping of Xenon Flash lamp illumination
Measurement duration	30Hz for data acquisition	125 ms for data acquisition
Measurement results	Given as relative value	Given in mm / sec
Numerical data	Blood flow Index	Velocity flow rate
Graphically data	Perfusion map of retina, Time variation of blood flow index	Path of flow
Illumination Light	LED (940nm)	12 V Halogen lamp

Item	LSFG-NAVI	RFI
Flash Exposure	Continuous exposure	Automatic, 1 ms pulse, train of up to 8 pulses, repetition rate 17.5ms.
Electrical Safety	IEC 60601-1:2012 IEC 60601-1-2: 2007	IEC 60601-1: 1st Ed. IEC 60601-1-2: 1st Ed.
Performance Standard	ISO 15004-2:2007 ISO 10940: 1998 ISO 60825-1: 2007 ISO 14971: 2007	ISO 15004: 1st Ed. ISO 14940: 1998 ANSI RP-27-1-96: 1st Ed.

Although there is technological difference between two devices, the results of nonclinical testing, including electrical safety and electromagnetic compatibility along with the software validation and verification, demonstrated the safety and effectiveness of LSFG-NAVI with the predicate device and did not raise a new concern for safety and/or effectiveness.

Both devices are ophthalmic imaging management systems where intended use for both devices is to capture, display, and store images of the retina to monitor the blood flow in retinal vessels for their quantitative evaluation.

The comparison of the technological characteristics

LSFG-NAVI selected The Retinal Functional Imager (RFI) - K062416 as the predicated device, and examined the substantial equivalence to its predicate device. The intended use and function are primarily equivalent and did not identify any new problem in safety and effectiveness.