May 30, 2018

CenterVue S.p.A
Roberto Gabriotti
Quality and Regulatory Affairs Manager
via San Marco 9h
35219 Padova, ITALY

Re: K180293
Trade/Device Name: Retia 2
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: MYC
Dated: March 27, 2018
Received: April 2, 2018

Dear Roberto Gabriotti:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/202
See PRA Statement below.

510(k) Number *(if known)*

K180293

Device Name

RETIA 2

Indications for Use *(Describe)*

The CenterVue RETIA 2 is a confocal scanning ophthalmoscope indicated for infrared and auto-fluorescence imaging of a human retina with or without the use of a mydriatic agent.

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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FORM FDA 3881 (7/17)

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K180293

510(k) Summary

Proprietary Name:	RETIA 2
Type of submission:	Traditional
Date of submission:	January 29th, 2018
Last revised on:	May 25th, 2018
Manufacturer:	CENTERVUE S.p.A. Via San Marco 9H 35129 Padova – ITALY
Applicant and contact	Mr. Roberto Gabriotti Centervue S.p.A. Manager of Quality and Regulatory Affairs Via San Marco 9H, 35129 Padova - ITALY Phone: +39 049 501 8399 Fax: +39 049 501 8398 Email: roberto.gabriotti@centervue.com
Product Code:	MYC
Regulation Number:	886.1570
Common Name:	Ophthalmoscope
Panel:	Ophthalmic
Class:	Class II
Indications for Use:	The CenterVue RETIA 2 is a confocal scanning ophthalmoscope indicated for infrared and auto-fluorescence imaging of a human retina with or without the use of a mydriatic agent.

Device description

The CenterVue RETIA 2 is a modification of the CenterVue EIDON (K142047).

RETIA 2 is a scanning ophthalmoscope which uses infrared light to obtain infrared-reflectance images of the retina and blue light to obtain auto-fluorescence images of the retina.

RETIA 2 operates as a standalone unit, running a dedicated software application, intended for prescription use only, and includes:

1. Optical head, including a removable lens cap;
2. Patient head-rest, including removable front-rest;
3. Patient chin rest;
4. Base, including touch-screen device (tablet with magnetic holder and USB cable), USB joystick and an external power supply.

RETIA 2 operates based on the following principles:

a) An illumination system consisting of infrared LEDs (850nm, 940nm), a blue LED (450nm) and a green LED illuminates the patient eye with the following functionality:
   - The IR LED with a centroid wavelength of 850 nm allows the capture of IR photos. The patient's retina is uniformly illuminated by a line in a horizontal direction. An oscillating mirror scans the line in order to illuminate the retina with a field of view of 60°.
   - Two IR LEDs with a centroid wavelength of 940 nm are seen from the eye in a free viewing system. The two LEDs are equally shifted with respect to the machine's optical axis. The LEDS are switched on during all exams in order to enable pupil tracking.
   - The blue LED (450 nm) is used to illuminate the retina and capture fluorescence retinal images. The retina is uniformly illuminated by a line in a horizontal direction. An oscillating mirror scans the line in order to illuminate the retina with a field of view of 60°.
   - The green LED is used as fixation target.

b) An imaging system including a barrier filter (high-pass with a cutoff at 500 nm) stops back-reflected light from the retina and only allows fluorescent light to be detected for imaging. A focusing lens is included in the imaging path to achieve optimal retinal focusing on a CMOS camera having a resolution of 5 megapixels.

c) An anterior segment alignment system is included, using two cameras and the two IR LEDs. The LEDs illuminate the anterior segment by diffusion, whereas the cameras allow a stereoscopic reconstruction of the pupil's position to be obtained with respect to the instrument's front lens.

RETIA 2 interacts with the patient by directing infrared- and blue-wavelength illumination for imaging purposes and green illumination for fixation purposes into the patient's eye. The chin-rest and head-rest are the only parts of the device that contact the patient. The chin-rest includes a patient proximity sensor and is motorized for height adjustment.

TECHNICAL SPECIFICATIONS

Class and type of applied part

- Class I, Type B (according to IEC 60601-1)

IP classification:

- IPX0 (according to the degree of protection provided by the enclosure with respect to harmful penetration of particulate matter or water).

Image acquisition:

- Non-mydriatic (minimum pupil size 2.5 mm)
- Field of view: 60° (H) x 55° (V) captured in a single exposure
- Sensor size: 5 Mpixel (2592 x 1944)
- Light source: near infrared (825-870 nm) and blue LED (440-475 nm)
- Working distance: 28 mm
- Resolution: 30 pixels/deg
- Resolution on retina: 17 microns
- Pixel pitch: 9.3 µm

Other features:

- Imaging modalities: IR, auto-fluorescence
- Automatic operation: auto-alignment, auto-focus, auto-exposure, auto-capture
- Auto-focusing adjustment range: -12D to +15D
- Dynamic, programmable internal fixation target, in every position of the field
- Tablet operated, with multi-touch, color display
- Ethernet connection through device
- Embedded hard disc (SSD)

Dimensions:

- Weight: 25 Kg
- Size: 620 X 590 X 360 mm

Power supply:

- Voltage: 12 V DC
- Power consumption: 60 W

Comparison with predicate device

The predicate device selected for comparison with the CenterVue RETIA 2 is identified as follows:

Proprietary Name:	EIDON
Manufacturer:	CenterVue S.p.A.
510(k) Number:	K142047
Clearance Date:	12 November 2014
FDA Product Code:	MYC
Classification Name:	Ophthalmoscope, Laser, Scanning[1]
Regulation Number:	886.1570

The following device was used as reference:

Proprietary Name:	SPECTRALIS
Manufacturer:	Heidelberg Engineering Gmbh
510(k) Number:	K172649
FDA Product Code:	MYC
Classification Name:	Ophthalmoscope, Laser, Scanning
Regulation Number:	886.1570

The Subject Device and the Predicate Device share many identical or similar properties and features. In particular, the fundamental scientific technology of the subject device is unchanged from the predicate and remains *confocal, line scanning, LED-based, ophthalmoscopy.* Also, the principle of operation, mechanism of action and interaction with the patient are unchanged.

With respect to EIDON, the RETIA 2 includes some modifications which enable it to capture fundus auto-fluorescence images, using the same base technology and maintaining the same Intended Use and Indications for Use.

Specifically, functional differences between RETIA 2 and EIDON are as follows:

- RETIA 2 does not allow the capture of color images, using white light;
- RETIA 2 allows the capture of auto-fluorescence images, using blue LED light.

Technological differences between RETIA 2 and EIDON include:

Characteristic	**CenterVue EIDON**	**CenterVue RETIA 2**
Imaging system	Scanning LED imaged to CMOS sensor	Scanning LED imaged to CMOS sensor with barrier filter for auto-fluorescence imaging
Imaging sensor	Color CMOS, 4608x3288 pixels (14 MP)	Monochrome CMOS, 2592x1944 pixels (5 MP)
Visible light source for imaging	Blue LED and white LEDs	Blue LED (more powerful)
Imaging modalities	Infrared, color, red-free	Infrared, auto-fluorescence

[1] Neither the CenterVue EIDON nor the RETIA 2 contain lasers but rather use LEDs for confocal imaging

Characteristic	CenterVue EIDON	CenterVue RETIA 2
Flash control electronic board		The board contains some modifications needed to drive the modified blue LED
Software		The device software is modified to implement fundus auto-fluorescence imaging and remove color retinal imaging

None of these differences have any significant effect on safety or effectiveness of the Subject Device.
Notably, with respect to the impact of these design modifications on a key part of the product's risk analysis (i.e. optical radiation safety), Centervue has confirmed continued conformance with the applicable recognized standard, ISO 15004-2, making these modifications eligible for a Special 510(k) notification.

Performance data – Bench

Continued conformance with the following standards has been confirmed in support of the substantial equivalence determination:

ISO 15004-2 (light Hazard Protection)
RETIA 2 fulfills the requirements for a group 1 determination according to ISO 15004-2:2007, i.e. ophthalmic instruments for which no potential light hazard exists.

ISO 15004-1
The subject device complies with the ISO 15004-1:2006 standard for ophthalmic instruments.

Electrical safety and electromagnetic compatibility
The device complies with IEC 60601-1:2005 and IEC 60601-1-2:2007.

IEC 62304
The device software complies with IEC 62304.

ISO 10940
RETIA 2 complies with the applicable requirements of ISO 10940 - Ophthalmic instruments — Fundus Cameras.

Performance data - Clinical

The imaging properties of the RETIA 2 were assessed by comparing infrared images taken with the RETIA 2 with infrared images taken using the predicate device (CenterVue EIDON, K142047) and by comparing autofluorescence images taken with the RETIA 2 with auto-fluorescence images taken with the reference device (Heidelberg SPECTRALIS, K172649). Images of eyes with and without diagnosed pathology were included in the comparison.
The comparison showed that RETIA 2 provides infrared and autofluorescence images that are similar to those of the mentioned devices.

Conclusion

Based on the information contained within this submission, it is concluded that the CenterVue RETIA 2 is substantially equivalent to the identified predicate devices already in interstate commerce within the USA.