July 16, 2018

CenterVue SpA
Roberto Gabriotti
Quality and Regulatory Affairs Manager
Via S. Marco 9H
Padova, 35129 ITALY

Re: K180526
Trade/Device Name: EIDON FA
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: MYC
Dated: June 5, 2018
Received: June 7, 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 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,

Alexander Beylin -S
2018.07.16 16:50:49 -04'00'

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

510(k) Number *(if known)*

K180526

Device Name

EIDON FA

Indications for Use *(Describe)*

The CenterVue EIDON FA is a confocal scanning ophthalmoscope indicated for color, infrared and auto-fluorescence imaging and fluorescein angiography 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.

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

Regulatory information

Device Name:	EIDON FA
Type of 510(k) submission:	Traditional
Date summary prepared:	July 3rd, 2018
Manufacturer:	CenterVue S.p.A. via San Marco 9h 35129 Padova Italy
510(k) Submitter 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 E-mail: roberto.gabriotti@centervue.com
Product Code:	MYC
Regulation Number:	886.1570
Classification Name:	Ophthalmoscope, Laser, Scanning
Panel:	Ophthalmic
FDA Classification:	Class II
Indications for use:	The CenterVue EIDON FA is a confocal scanning ophthalmoscope indicated for color, infrared and auto-fluorescence imaging and fluorescein angiography of a human retina with or without the use of a mydriatic agent.

centervue

Device description

The CenterVue EIDON FA has been derived from the CenterVue EIDON, a retinal imaging device cleared under K142047. EIDON FA is a scanning ophthalmoscope which uses LED light to capture confocal images of the retina. In particular, EIDON FA uses infrared light to obtain infrared-reflectance images, white light to obtain color images and blue light to obtain auto-fluorescence and fluorescence images. EIDON FA can be used with or without pharmacological dilation.

The CenterVue EIDON FA is part of a family of devices, which includes three models: EIDON FA, EIDON AF, and EIDON. EIDON is the base model, which features the following imaging modalities: infrared reflectance, color and red-free. EIDON AF adds autofluorescence imaging to the base model. The EIDON FA is the fully featured device, which adds fluorescein angiography to the capabilities of the EIDON AF and encompasses the features and functionality of the other models.

EIDON FA operates as a standalone unit, running a dedicated software application, is intended for prescription use only, and includes:

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

EIDON FA operates based on the following principles:

a) An illumination system consisting of an infrared (IR) LED (825-875 nm and 940 nm), a white LED (440-650 nm), a blue LED (440-475 nm) and a green LED, illuminates the patient eye with the following functions:
   - the IR LED with central wavelength at 850 nm allows the capture of IR photos. The patient's retina is uniformly illuminated by a line in a horizontal direction. Along the optical path there is an oscillating mirror which scans the line in order to illuminate the retina with a field of view of 60°.
   - Two IR LEDs with central wavelength at 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 white and blue LEDs allow the capture of color photos. The retina is uniformly illuminated by a line in the horizontal direction. Along the optical path an oscillating mirror scans the line in order to illuminate the retina with a field of view of 60°.
   - The blue LED is also used to capture auto-fluorescence and fluorescence retinal images;
   - 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 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.

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.

centervue

EIDON FA interacts with the patient by directing infrared, white, blue (for imaging) and green (for fixation) illumination 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:
- Minimum pupil size: 2.5 mm
- Field of individual image: 60° (H) x 55° (V) captured in a single exposure
- Sensor resolution: 14 MP (4608x3288 pixels)
- Light sources: infrared LED (825-870 nm), white LED (440-650 nm), blue LED (440-475nm)
- Imaging modalities: color, red-free, IR reflectance, autofluorescence (AF), fluorescein angiography (FA)
- Working distance: 28 mm
- Resolution: 60 pixels / deg.
- Resolution on retina: 15 microns
- Pixel pitch: 4.9 µm
- FA video resolution: 1840x1622 pixels
- FA video acquisition rate: 5 fps

DICOM:
- Compatibility: DICOM version 3.0

Other features:
- Automatic operation: auto-alignment, auto-focus, auto-exposure, auto-capture
- Focus adjustment range: -12D to +15D
- Internal fixation target: dynamic, programmable
- Display: 10.1" multi-touch, color tablet
- Hard disk: SSD, 2 TB

Dimensions:
- Weight: 25Kg (55lb)
- Size (W x H x D): 360mm x 590mm x 620mm (14.2" x 23.2" x 24.4")

centervue

Power supply:

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

Predicate devices

The predicate devices selected for comparison with EIDON FA are identified as follows:

Predicate Device 1 (primary):

Device Name:	**EIDON**
Manufacturer:	CenterVue S.p.A.
510(k) Number:	K142047
Product Code:	MYC
Classification Name:	Ophthalmoscope, Laser, Scanning[1]
Regulation No:	886.1570

Predicate Device 2:

Device Name:	**KOWA VX-20**
Manufacturer:	Kowa Company, Ltd.
510(k) Number:	K112330
Product Code:	HKI, NFJ
Classification Name:	Camera, Ophthalmic, AC-powered
Regulation No:	886.1120

Predicate Device 3:

Device Name:	**Spectralis HRA[2]**
Manufacturer:	Heidelberg Engineering Gmbh
510(k) Number:	K172649
Product Code:	MYC
Classification Name:	Ophthalmoscope, Laser, Scanning
Regulation No:	886.1570

Comparison of technological characteristics with the predicate device(s)

The following technological differences exist between the subject device and the primary predicate device:

Difference	Equivalence discussion
Capability for autofluorescence imaging, driving the blue LED at higher power and using an insertable barrier filter	No additional concerns for safety and effectiveness as the subject device is equivalent to the primary predicate in terms of safety and to the Spectralis HRA in terms of effectiveness
Capability for fluorescein angiography driving the blue LED at higher power,	No additional concerns for safety and effectiveness as the subject device is equivalent to the KOWA VX-

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

[2] The Spectralis is considered only in relation to its imaging functions, while the OCT function is not relevant

centervue

firing the flash at higher frequency and using an insertable barrier filter	20 in terms of safety and equivalent to the Spectralis HRA in terms of effectiveness

Performance data - bench

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

Electrical safety and electromagnetic compatibility (EMC)
The device complies with the IEC 60601-1:2005 and IEC 60601-1-2:2007 standards.

Software Verification and Validation Testing
Software verification and validation testing were 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 as a "moderate" level of concern, since a failure or latent flaw in the software could directly result in minor injury. The software also complies with the IEC 62304 standard for software life cycle processes.

Fundus cameras testing
The device complies with the ISO 10940:2009 standard for fundus cameras.

Light hazard testing
The device complies with the ISO 15004-1:2006 standard for ophthalmic instruments and with the ISO 15004-2:2007 standard for light hazard protection.

Performance data - clinical

The imaging properties of the EIDON FA were assessed by comparing color and infrared images taken with EIDON FA with the same images taken using the primary predicate device (CenterVue EIDON, K142047) and by comparing auto-fluorescence and fluorescein angiography images taken with EIDON FA with the same images taken using predicate device 3 (Heidelberg SPECTRALIS, K172649). Images of eyes with and without diagnosed pathology were included in the comparison. The comparison showed that EIDON FA provides in all modalities images that are similar to those of the mentioned devices.

Conclusions

Based on the information contained within this submission, it is concluded that the CenterVue EIDON FA is substantially equivalent to the identified predicate devices already in interstate commerce within the USA, and that any differences that do exist have no effect on the safety and effectiveness of the device.