August 19, 2021

CenterVue SpA
Luca Scienza
Quality and Regulatory Affairs Manager
Via S. Marco 9H
Padova, 35129
Italy

Re: K211328
Trade/Device Name: Eidon Fa, Eidon, Eidon Af, Eidon Uwfl
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: MYC
Dated: July 12, 2021
Received: July 14, 2021

Dear Luca Scienza:

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
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: 06/30/2023
See PRA Statement below.

510(k) Number: K211328

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)

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510(k) Summary

Proprietary Name(s):	EIDON FA, EIDON, EIDON AF, EIDON UWFL
Type of submission:	Special
Date of preparation:	August 10th, 2021
Manufacturer:	CENTERVUE S.p.A. Via San Marco 9H 35129 Padova – ITALY
Submitter and contact	Mr. Luca Scienza 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: luca.scienza@icare-world.com
Product Code:	MYC
Regulation Number:	886.1570
Common Name:	Ophthalmoscope
Panel:	Ophthalmic
Class:	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.
Legally marketed device (Predicate)	EIDON FA (K180526)

Device description

The CenterVue EIDON FA with Software version 4.0 and Ultra Widefield Lens is a modification of the CenterVue EIDON FA (K180526).

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 EIDON FA (K180526) is a scanning ophthalmoscope which uses white light to obtain color images of the retina, infrared light to obtain infrared-reflectance images of the retina, and blue light to obtain autofluorescence and fluorescence images.
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.
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.

With respect to the CenterVue EIDON FA, EIDON FA with software version 4.0 provides additional features to acquire retinal images with the Ultra Widefield Lens. The optional Ultra Widefield Lens increases the field of view of the devices from 60° to 80°. All the features related to the acquisition without the Ultra Widefield Lens are unchanged.

The modified devices use the same base technology and maintains the same Intended Use and Indications for Use of the predicate device.

The fundamental scientific technology of the subject device is unchanged from the predicate and remains *confocal, line scanning, LED-based, imaging.*

The functional differences between EIDON FA and EIDON FA with software version 4.0 are as follows:

- EIDON FA with software version 4.0 allows to capture retinal picture with an increased field of view, from 60° to 80° to allow the user to view a greater proportion of the posterior eye in one view.
- EIDON FA with software version 4.0 allows to capture Ultra Widefield images with the same modalities of the unmodified device, namely: color images, infrared-reflectance images, autofluorescence images and fluorescence images.

No technological differences between EIDON FA and EIDON FA with SW version 4.0 exist.

- The modified device can be used with or without the Ultra Widefield Lens. The technological principle of retinal acquisitions remains the same in the modified device.
- The device software has been modified to implement the acquisition and management of images taken with the Ultra Widefield Lens.

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The EIDON UWFL – Ultra Widefield Lens accessory is composed of a lens doublet, assembled in a custom lens holder, which can be mounted on the standard objective of the parent device by means of an incorporated threaded ring to increase the field of view of the parent device from 60° (standard objective) to 80° (with UWFL).

The CenterVue EIDON UWFL – Ultra Widefield Lens is an optional accessory to extend the field of view of the CenterVue EIDON, EIDON AF and EIDON FA from 60° to 80°. It is indicated for color, infrared and auto-fluorescence imaging and fluorescein angiography of a human retina with or without the use of a mydriatic agent.

The principle of operation of the EIDON UWFL is an increase of the divergence of the standard objective to achieve a greater field of view.

The mechanism of action and the conditions for use are the same of the predicate device.

Other than the above, no differences exist between the EIDON FA and EIDON FA with Ultra Widefield Lens, in particular the principle of operation, mechanism of action and interaction with the patient are unchanged.

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 (non-mydriatic use)
• Field of view:	60° (H) x 55° (V) captured in a single exposure 80° (H) x 75° (V) captured in a single exposure, with Ultra Widefield Lens
• Sensor size:	14 Mpixel (4608x3288)
• Light source:	infrared LED (825-870 nm), white LED (440-650 nm), blue LED (440-475 nm)
• Imaging modalities:	color, red-free, IR reflectance, autofluorescence (AF), fluorescein-angiography (FA)
• Working distance:	28 mm 16 mm, with Ultra Widefield Lens
• Resolution:	60 pixels/deg (centre of the field) 45 pixels/deg (centre of the field), with Ultra Widefield Lens
• Resolution on retina:	15 microns 17 microns, with Ultra Widefield Lens

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- Pixel pitch: 4.9 microns
  6.34 microns, with Ultra Widefield Lens
- FA video resolution: 1840x1622 pixels
- FA video acquisition rate: 5 fps

Other features:

- Automatic operation: auto-alignment, auto-focus, auto-exposure, auto-capture
- Focus adjustment range: -12 D to +15 D
  -8 D to +8 D with Ultra Widefield Lens
- Internal fixation target: dynamic, programmable
- Display: 10.1" multi-touch, color tablet

Dimensions:

- Weight: 25 Kg (55 lbs)
- Size: 620 X 590 X 360 mm (14.2" x 23.2" x 24.4")

Power supply:

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

Comparison with predicate device

The predicate device selected for comparison with the CenterVue EIDON FA with software version 4.0 and Ultra Widefield Lens is identified as follows:

Proprietary Name:	EIDON FA
Manufacturer:	CenterVue S.p.A.
510(k) Number:	K180526
Clearance Date:	12 July 2018
FDA Product Code:	MYC
Classification Name:	Ophthalmoscope, Laser, Scanning[1]
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 FA, the EIDON FA with software 4.0 includes includes the possibility to equip the devices of the family with an optional Ultra Widefield Lens, to increase the field of view of the devices from 60° to 80°, using the same base technology and maintaining the same Intended Use and Indications for Use.

The functional differences between EIDON FA and EIDON FA with software version 4.0 are as follows:

- EIDON FA with software version 4.0 allows to capture retinal picture with an increased field of view, from 60° to 80° to allow the user to view a greater proportion of the posterior eye in one view.
- EIDON FA with software version 4.0 allows to capture Ultra Widefield images with the same modalities of the unmodified device, namely: color images, infrared-reflectance images, autofluorescence images and fluorescence images.

No technological differences between EIDON FA and EIDON FA with SW version 4.0 exist.

- The modified device can be used with or without the Ultra Widefield Lens. The technological principle of retinal acquisitions remains the same in the modified device.
- The device software has been modified to implement the acquisition and management of images taken with the Ultra Widefield Lens.

Other than the above, no differences exist between the EIDON FA and EIDON FA with software 4.0 and Ultra Widefield Lens, in particular the principle of operation, mechanism of action and interaction with the patient are unchanged.
None of these differences have any significant effect on safety or effectiveness of the Subject Device.

[1] Neither the CenterVue EIDON FA nor the EIDON FA with software 4.0 contain lasers but rather use LEDs for confocal imaging

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, ANSI Z80-36:2016, making these modifications eligible for a Special 510(k) notification.

Performance data

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

ANSI Z80-36 (Light Hazard Protection)

EIDON FA with software version 4.0 and Ultra Widefield Lens fulfills the requirements for a group 2 determination according to ANSI Z80-36, i.e. ophthalmic instruments with potential light hazard.

ISO 15004-1

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

IEC 62304

The subject device software complies with IEC 62304.

ISO 10940

EIDON FA with software version 4.0 and Ultra Widefield Lens fully complies with the applicable requirements of ISO 10940 - Ophthalmic instruments — Fundus Cameras when used without the optional lens, and partially complies with applicable requirements of ISO 10940 when used with the optional lens mounted.

Clinical summary

The imaging capabilities of EIDON FA with UWFL were assessed by comparing the following Subject and Predicate devices in the listed Imaging Modalities:

SUBJECT DEVICE	PREDICATE DEVICE	IMAGING MODALITIES
EIDON FA with Software version 4.0 and Ultra Widefield Lens	EIDON FA	Infrared Color Autofluorescence Fluorescein Angiography

The data were collected at four different sites located in Italy. Each eye was tested with **Eidon FA with and without the lens** in random order. Patients were tested according to booked appointments for the day: no patients pre-selection was performed based on gender, age, ethnicity, or any other factors. The imaging modality was selected according to the clinician's decision for each patient.

For infrared and color images, eyes with and without diagnosed pathology were included in the comparison. For Infrared images, 10 eyes which presented without pathology and the 8 eyes which presented with pathology were provided in a side-by-side comparison.

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For Color images, 11 eyes which presented without pathology and 10 eyes which presented with pathology were provided in a side-by-side comparison.
Since red-free images are obtained in EIDON FA as the green channel of the color image, comparison of color images also yields for red-free imaging.

For autofluorescence and fluorescein angiography 10 eyes and 11 eyes respectively, with diagnosed pathology which presented were provided.
As images included have a different field of view between the two devices, namely 60° for the CenterVue EIDON FA and 80° for CenterVue EIDON FA with UWFL, only the inner 60° of the 80° images should be used for comparison.
For fluorescein angiography, direct comparison of images captured during the early phase is not possible as it would require simultaneous capture with and without the UWFL on the same device, so only intermediate and late phase images were compared. It should also be noted that, due to the need to remove the lens and resume the acquisition, FA images with and without the UWFL were taken at different times from fluorescein injection.

The comparison shows that EIDON FA with software version 4.0 and UWFL provides images that are similar in the central 60° to those of the cleared device, for all imaging modalities.

Conclusion

Based on the information contained within this submission, it is concluded that the CenterVue EIDON FA with software version 4.0 and Ultra Widefield Lens is substantially equivalent to the identified predicate devices already in interstate commerce within the USA.