December 21, 2021

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

Re: K213705
Trade/Device Name: DRSplus
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: MYC
Dated: November 19, 2021
Received: November 24, 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,

for 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 *(if known)*
K213705

Device Name
DRSplus

Indications for Use *(Describe)*

The CenterVue DRSplus is a confocal scanning ophthalmoscope indicated for color and infrared imaging of a human retina 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.

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centervue

510(k) Summary

Proprietary Name(s):	DRSplus
Type of submission:	Special
510(k) submission:	K213705
Date of submission:	November 19th, 2021
Manufacturer:	CENTERVUE S.p.A. Via San Marco 9H 35129 Padova – ITALY
Applicant 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 DRSplus is a confocal scanning ophthalmoscope indicated for color and infrared imaging of a human retina without the use of a mydriatic agent.

Predicate Device Information

Proprietary name:	DRSplus
510(k):	K192113
Product Code:	MYC
Regulation number:	886.1570
Common name:	Ophthalmoscope
Panel:	Ophthalmic
Class:	II
Indication for use	The CenterVue DRSplus is a confocal scanning ophthalmoscope indicated for color imaging of a human retina without the use of a mydriatic agent.

Reference Device Information

Proprietary name:	EIDON
510(k):	K142047
Product Code:	MYC
Regulation number:	886.1570
Common name:	Ophthalmoscope
Panel:	Ophthalmic
Class:	II
Indication for use:	The CenterVue EIDON is intended for taking digital images of a human retina without the use of a mydriatic agent. The reference device has been included only in the context of image comparison, as no comparison of Infrared Imaging Modality is possible between the subject device and the predicate device.

Device description

The CenterVue DRSplus with Software version 2.0 is a modification of the CenterVue DRSplus (K192113).

The DRSplus (K192113) is a scanning ophthalmoscope which uses infrared and white light to obtain confocal images of the retina, without pharmacological dilation.

With respect to the previous cleared device, DRSplus with software version 2.0 (subject of this submission) provides one additional software feature that enable to acquire, store and review infrared retinal images, in addition to color and red-free photos which were the only imaging modalities of the previously cleared device.

This feature does not require any hardware modification, because the infrared illumination is already present in the previously cleared device: in fact, the infrared retinal pictures were automatically taken by the device for alignment and focusing purposes, but they were not presented in the patient's image collection. In the proposed device modification, the user can decide to acquire also infrared pictures that are stored and displayed amongst the other, color and red-free images.

The modified device uses the same base technology and maintains the same Intended Use of the previously cleared device; the Indications for Use of the modified device are amended to add the infrared imaging modality.

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

The functional differences between DRSplus with software version 2.0 and the previously cleared device are as follows:

- DRSplus with software 2.0 allows the user to take also IR pictures of the retina;
- DRSplus with software 2.0 allows the user to save and review IR pictures of the retina.

No technological differences between DRSplus with software version 2.0 and the previously cleared device exist. In particular:

- DRSplus with software version 2.0 uses the same technological principle of retinal acquisitions of the cleared device;
- DRSplus with software version 2.0 uses the same illuminator, illumination optics and viewing optics of the cleared device.

Other than the above, no other differences exist between the DRSplus with software version 2.0 and the previously cleared device, in particular the principle of operation, mechanism of action and interaction with the patient are unchanged.

TECHNICAL SPECIFICATIONS of the DRSplus with Software version 2.0

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: 3.2 mm (non-mydriatic use)
- Field of view: 45° (H) x 40° (V) captured in a single exposure
- Sensor size: 3600 x 2910 (10 MP)
- Light source: infrared LED (825-870 nm), white LED (420-675 nm)
- Imaging modalities: color, red-free, infrared
- Working distance: 25 mm
- Pixel pitch: 3.7 µm

Other features:

- Automatic operation: auto-alignment, auto-focus, auto-exposure, auto-capture
- Focus adjustment range: -15 D to +15 D
- Internal fixation target: 10 positions
- Display: 10.1” multi-touch, color
- Hard disk: SSD, 512 GB

Dimensions:

- Weight: 11 Kg (24 lbs)
- Size (W x H x D): 300 X 450 X 650 mm (11.8” x 17.7” x 25.6”)

Power supply:

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

Comparison with previously cleared device

The previously cleared device is identified as follows:

Proprietary Name:	DRSplus
Manufacturer:	CenterVue S.p.A.
510(k) Number:	K192113
Clearance Date:	25 November 2019
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 the previous cleared device, DRSplus with software version 2.0 (subject of this submission) provides one additional software feature that enable to acquire, store and review infrared retinal images, in addition to color and red-free photos which were the only imaging modalities of the previously cleared device.

The functional differences between DRSplus with software version 2.0 and the previously cleared device are as follows:

- DRSplus with software 2.0 allows the user to take also IR pictures of the retina;
- DRSplus with software 2.0 allows the user to save and review IR pictures of the retina.

No technological differences between DRSplus with software version 2.0 and the previously cleared device exist. In particular:

- DRSplus with software version 2.0 uses the same technological principle of retinal acquisitions of the cleared device;
- DRSplus with software version 2.0 uses the same illuminator, illumination optics and viewing optics of the cleared device.

Other than the above, no other differences exist between the DRSplus with software version 2.0 and the previously cleared device, 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.
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, as no modification has been introduced in the illumination and viewing systems.

[1] Neither the CenterVue DRSplus nor the DRSplus with software 2.0 contain lasers but rather use LEDs for confocal imaging

Performance data

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

ANSI Z80-26 (light Hazard Protection)
DRSplus with software version 2.0 fulfills the requirements for a Group 1 determination according to ANSI Z80-36.

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
DRSplus with software version 2.0 fully complies with the applicable requirements of ISO 10940 - Ophthalmic instruments — Fundus Cameras.

Clinical data

No clinical data required to evaluate the proposed change, only image comparisons are provided.

Conclusion

Based on the information contained within this submission, it is concluded that the CenterVue DRSplus with software version 2.0 is substantially equivalent to the previously cleared device already in interstate commerce within the USA.