November 15, 2019

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

Re: K192113
Trade/Device Name: DRSplus
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: MYC
Dated: October 7, 2019
Received: October 10, 2019

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. 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 Tieuvi Nguyen, Ph.D.,
Acting 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: 06/30/202
See PRA Statement below.

510(k) Number *(if known)* K192113

Device Name

DRSplus

Indications for Use *(Describe)*

The CenterVue DRSplus is a confocal scanning ophthalmoscope indicated for color 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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510(K) SUMMARY

Regulatory information

Device Name:	DRSplus
Type of 510(k) submission:	Traditional
Date summary prepared:	November 8th, 2019
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: Classification	886.1570
Name:	Ophthalmoscope, Laser, Scanning
Panel:	Ophthalmic
FDA Classification:	Class II
Indications 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.

Device description

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

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

1. an optical head;
2. a patient forehead rest;
3. a display;
4. a base;
5. a stand.

The CenterVue DRSplus operates based on the following principles:

a) An illumination system consisting of infrared (IR) LEDs, white LEDs and a green LED illuminates the patient eye with the following functions:
   - the IR LED allows the capture of IR photos, which are used for alignment and focusing purposes. The patient's retina is uniformly illuminated by a line in the horizontal direction. Along the optical path there is an oscillating mirror which scans the line in order to illuminate the retina.
   - Two IR LEDs 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 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.
   - The green LED is used as fixation target.

b) An imaging system collects back-reflected light from the retina and creates a high-resolution image. 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.

The DRSplus interacts with the patient by directing infrared, white (for imaging) and green (for fixation) illumination into the patient's eye. The forehead-rest is the only part of the device that contacts the patient.

Technical Specifications

Class and type of applied part
Class I, Type B (according to IEC 60601-1).

IP classification:
IP20 (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
- Field of individual image: 45° (H) x 40° (V) captured in a single exposure
- Image size: 3600 x 2910 pixels (10 MP)
- Light sources: infrared LED (825-870 nm), white LED (420-675 nm)
- Imaging modalities: color, red-free
- Working distance: 25 mm
- Pixel pitch: 3.7 microns

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): W 300mm x H 450mm x D 650mm

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

Predicate devices

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

Predicate Device:

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

Reference Device:

Device Name:	**DRS**
Manufacturer:	CenterVue S.p.A.
510(k) Number:	K101935
Product Code:	HKI
Classification Name:	Camera, ophthalmic
Regulation No:	886.1120

Comparison of technological characteristics with the predicate device(s)

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

Difference	Equivalence discussion
Infrared reflectance imaging is available with the DRSplus only for the purpose of alignment and focusing	No additional concerns for safety and effectiveness as this is a
Field of view is smaller	No additional concerns for safety and effectiveness as the subject device is equivalent to the reference device in terms of field
Minimum pupil diameter is slightly larger	No additional concerns for safety and effectiveness as the subject device is equivalent to the reference device in terms of minimum pupil size
Significantly smaller dimensions and lighter weight	No additional concerns for safety and effectiveness
Different technology is used to scan the illumination light onto the retina	No additional concerns for safety and effectiveness

Such differences are believed to have no effect on the safety and effectiveness of the device.

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

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 EN 60601-1:2006 and IEC 60601-1-2:2015 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 ANSI Z80.36-2016 standard for light hazard protection.

Performance data – Clinical
The imaging properties of the DRSplus were checked by comparing color images captured using the DRSplus and the predicate device EIDON. Images from randomly selected normal subjects and subjects with retinal pathologies were acquired at two different sites and included in the comparison. The two devices were alternated and patients were imaged without pharmacological pupil dilation. The comparison showed that the DRSplus provides images that are similar to those of the mentioned predicate device.

Conclusions

Based on the information contained within this submission, it is concluded that the CenterVue DRSplus 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.