November 1, 2017

Heidelberg Engineering GmbH
% Lena Sattler
Consultant
Orasi Consulting, LLC.
1655 Forest Dr.
Medina, OH 44256

Re: K172649
Trade/Device Name: Spectralis HRA + OCT and variants, Spectralis FA+OCT, Spectralis ICGA+OCT, Spectralis OCT Blue Peak, Spectralis OCT with Multicolor
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO, MYC
Dated: October 20, 2017
Received: October 23, 2017

Dear Lena Sattler:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172649

Device Name
Spectralis HRA+OCT and variants

Indications for Use *(Describe)*
The SPECTRALIS is a non-contact ophthalmic diagnostic imaging device. It is intended for viewing the posterior segment of the eye, including two- and three-dimensional imaging, cross-sectional imaging (SPECTRALIS HRA+OCT and SPECTRALIS OCT), fundus photography, fluorescence imaging (fluorescein angiography, indocyanine green angiography; SPECTRALIS HRA+OCT, SPECTRALIS HRA), autofluorescence imaging (SPECTRALIS HRA+OCT, SPECTRALIS HRA and SPECTRALIS OCT with BluePeak) and to perform measurements of ocular anatomy and ocular lesions. The device is indicated as an aid in the detection and management of various ocular diseases, including age-related macular degeneration, macular edema, diabetic retinopathy, retinal and choroidal vascular diseases, glaucoma, and for viewing geographic atrophy as well as changes in the eye that result from neurodegenerative diseases. The SPECTRALIS HRA+OCT and SPECTRALIS OCT include reference databases for retinal nerve fiber layer thickness and optic nerve head neuroretinal rim parameter measurements, which are used to quantitatively compare the retinal nerve fiber layer and neuroretinal rim in the human retina to values found in normal subjects.

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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HEIDELBERG ENGINEERING

510(K) SUMMARY - K172649

Date Prepared October 29, 2017

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COMMON/USUAL NAME

Optical Coherence Tomography

PROPRIETARY OR TRADE NAMES

SPECTRALIS HRA+OCT and variants

CLASSIFICATION INFORMATION

Classification Name:	Ophthalmoscope, AC Powered Ophthalmoscope, Laser, Scanning
Medical Specialty:	Ophthalmic
Device Class:	II
Classification Panel:	Ophthalmic Device Panel
Product Codes:	OBO, MYC

PRODUCT CODE: CLASSIFICATION / CFR TITLE

OBO, MYC:	Class II § 21 CFR 886.1570

LEGALLY MARKETED UNMODIFIED PREDICATE DEVICE

Trade/Device Name:	SPECTRALIS HRA+OCT and variants
Applicant:	Heidelberg Engineering GmbH
510(k) Premarket Notification number:	K152205
Classification:	Class II
CFR Title:	21 CFR 886.1570
FDA Product Code(s):	OBO, MYC
Classification Name:	Ophthalmoscope, AC Powered Ophthalmoscope, Laser, Scanning
Common Name:	Optical Coherence Tomography
Medical Specialty:	Ophthalmic
Classification Panel:	Ophthalmic Device Panel

The device name and classification information for the modified device is identical to the cleared device.

GENERAL DEVICE DESCRIPTION

The Heidelberg Engineering SPECTRALIS HRA+OCT is a device used to image the anterior and posterior segments of the human eye and to aid in the assessment and management of various diseases of the posterior segment, such as age-related macular degeneration, diabetic retinopathy, and glaucoma. The device is capable of acquiring infrared and blue reflectance images (K101223), as well as a composite color image referred to as "MultiColor image" due to addition of a green laser light source (K121993). New reference data for peripapillary retinal nerve fiber layer thickness and optic nerve head parameters have been added in K152205, as well as two (2) new accessory objective lenses (Wide Field, Ultra-Widefield), and OCT Enhanced Depth Imaging mode.

The modifications to the SPECTRALIS are:

1. OCT2 Module (OCT2) – replacement of the Line Scan Camera and PC interface. OCT2 was developed due to the discontinuation of components.

2. Wide Field Objective 2 (WFO2) – The WFO provides a 55° diameter circular field of view. The field of view can be reduced by the software to 35° and 25°. The AR-coating of the WFO was optimized in order to reduce the remaining

reflections at the MultiColor wavelengths 486 nm, 518 nm and 815 nm. The AR-coating also allows for MultiColor imaging.

3. An upgrade to the data and patient management system (Heyex 2). Heyex 2 has the same basic functionality as the data and patient management system of the cleared SPECTRALIS, Heyex 1. The main improvements of Heyex 2 compared to Heyex 1 are an up-to-date and more scalable underlying image database, and a modern User Interface.

4. Windows 10 Operating System support.

5. Labeling – The user manual has been updated to (1) improve clarity, (2) improve grammar and (3) include the modifications made to the SPECTRALIS HRA+OCT and variants. The Intended Use/Indications for Use of the modified device, as described in the labeling has not changed as a result of the modifications.

INDICATIONS FOR USE

The SPECTRALIS is a non-contact ophthalmic diagnostic imaging device. It is intended for viewing the posterior segment of the eye, including two- and three-dimensional imaging, cross-sectional imaging (SPECTRALIS HRA+OCT and SPECTRALIS OCT), fundus photography, fluorescence imaging (fluorescein angiography, indocyanine green angiography; SPECTRALIS HRA+OCT, SPECTRALIS HRA), autofluorescence imaging (SPECTRALIS HRA+OCT, SPECTRALIS HRA and SPECTRALIS OCT with BluePeak) and to perform measurements of ocular anatomy and ocular lesions. The device is indicated as an aid in the detection and management of various ocular diseases, including age-related macular degeneration, macular edema, diabetic retinopathy, retinal and choroidal vascular diseases, glaucoma, and for viewing geographic atrophy as well as changes in the eye that result from neurodegenerative diseases. The SPECTRALIS HRA+OCT and SPECTRALIS OCT include reference databases for retinal nerve fiber layer thickness and optic nerve head neuroretinal rim parameter measurements, which are used to quantitatively compare the retinal nerve fiber layer and neuroretinal rim in the human retina to values found in normal subjects.

SUBSTANTIAL EQUIVALENCE

The modified SPECTRALIS HRA+OCT and variants is a device modification to the cleared SPECTRALIS HRA+OCT and variants (K152205) predicate device. The modified SPECTRALIS has the same Intended Use/Indications for Use and the same fundamental scientific technology as the predicate device.

The Substantial Equivalence Summary tables below illustrate the comparisons of the modified SPECTRALIS to the predicate device.

The modified SPECTRALIS HRA+OCT and variants measures the same ophthalmic features and parameters as the cleared SPECTRALIS HRA+OCT and variants in K152205.

The changes applied to the SPECTRALIS since the clearance in K152205 do not change the subject population for whom the device is used, the type of images to be acquired, or the usefulness of the SPECTRALIS as a quantitative aid to an ophthalmologic examination of the eye.

Technological detail characteristics of the device are unchanged except for the modifications as stated in the General Device Description.

INTENDED USE/INDICATIONS FOR USE STATEMENT CHART

K152205 PREDICATE DEVICE	SUBJECT DEVICE	Same or Different
The SPECTRALIS is a non-contact ophthalmic diagnostic imaging device. It is intended for viewing the posterior segment of the eye, including two- and three-dimensional imaging, cross-sectional imaging (SPECTRALIS HRA+OCT and SPECTRALIS OCT), fundus photography, fluorescence imaging (fluorescein angiography, indocyanine green angiography; SPECTRALIS HRA+OCT, SPECTRALIS HRA), autofluorescence imaging (SPECTRALIS HRA+OCT, SPECTRALIS HRA and SPECTRALIS OCT with BluePeak) and to perform measurements of ocular anatomy and ocular lesions. The device is indicated as an aid in the detection and management of various ocular diseases, including age-related macular degeneration, macular edema, diabetic retinopathy, retinal and choroidal vascular diseases, glaucoma, and for viewing geographic atrophy as well as changes in the eye that result from neurodegenerative diseases. The SPECTRALIS HRA+OCT and SPECTRALIS OCT include reference databases for retinal nerve fiber layer thickness and optic nerve head neuroretinal rim parameter measurements, which are used to quantitatively compare the retinal nerve fiber layer and neuroretinal rim in the human retina to values found in normal subjects.	The SPECTRALIS is a non-contact ophthalmic diagnostic imaging device. It is intended for viewing the posterior segment of the eye, including two- and three-dimensional imaging, cross-sectional imaging (SPECTRALIS HRA+OCT and SPECTRALIS OCT), fundus photography, fluorescence imaging (fluorescein angiography, indocyanine green angiography; SPECTRALIS HRA+OCT, SPECTRALIS HRA), autofluorescence imaging (SPECTRALIS HRA+OCT, SPECTRALIS HRA and SPECTRALIS OCT with BluePeak) and to perform measurements of ocular anatomy and ocular lesions. The device is indicated as an aid in the detection and management of various ocular diseases, including age-related macular degeneration, macular edema, diabetic retinopathy, retinal and choroidal vascular diseases, glaucoma, and for viewing geographic atrophy as well as changes in the eye that result from neurodegenerative diseases. The SPECTRALIS HRA+OCT and SPECTRALIS OCT include reference databases for retinal nerve fiber layer thickness and optic nerve head neuroretinal rim parameter measurements, which are used to quantitatively compare the retinal nerve fiber layer and neuroretinal rim in the human retina to values found in normal subjects.	Same

INTENDED USE CHARACTERISTICS CHART

	PREDICATE DEVICE K152205 SPECTRALIS HRA+OCT	SUBJECT DEVICE	Same or Different
User	Ophthalmologist, office setting	Ophthalmologist, office setting	Same
Eye contact required?	No	No	Same
Dilation of pupil required?	No	No	Same
Working position	The patient is sitting straight in front of the device. The examiner is sitting opposite the patient.	The patient is sitting straight in front of the device. The examiner is sitting opposite the patient.	Same
Images of posterior segment of eye	Yes, using standard, WFO, or UWF objective lens	Yes, using standard, WFO / WFO2, or UWF objective lens	Same; WFO2 was introduced, which has an enhanced anti-reflective coating, but offers the same field of view and has the same optical design.
Images of anterior segment of eye	With Anterior Segment Module (K113129)	With Anterior Segment Module (K113129)	Same
RNFL Reference Database	RNFL thickness in reference database for 12° circle scans (K101223) RNFL thickness in reference database for fixed diameter circle scans (K152205)	RNFL thickness in reference database for 12° circle scans (K101223) RNFL thickness in reference database for fixed diameter circle scans (K152205)	Same
ONH Reference Database	ONH parameters (BMO-MRW, BMO-MRA) reference database (K152205)	ONH parameters (BMO-MRW, BMO-MRA) reference database (K152205)	Same

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NON-CLINICAL PERFORMANCE SUMMARY

The modified SPECTRALIS was evaluated according to the requirements of FDA recognized consensus standards ISO 14971, AAMI / ANSI ES60601-1:2005, IEC 60601-1-2 Edition 3: 2007-03, ISO 10993-1 Fourth Edition 2009-10-15, AAMI/ANSI/ISO 10993-5:2009/(R) 2014, ISO 10993-12 Fourth Edition 2012-07-01, ISO 10993-18:2005, IEC 60825-1 Edition 2.0 2007-03, and AAMI / ANSI / IEC 62304:2006 and was found to meet the requirements of the applicable parts.

DESIGN CONTROL

Heidelberg Engineering designed and developed the modified SPECTRALIS per the company's Design Control procedure, which complies with the FDA Quality System Regulations CFR Part 820 and ISO 13485:2012. The Design Control procedure also incorporates Risk Management procedures, which comply with ISO 14971:2007.

Risk assessment was conducted on the modified SPECTRALIS, and the impact of the design modifications were assessed on the predicate 510(k) cleared device.

The modified SPECTRALIS is manufactured and tested in the exact manner as the predicate 510(k) cleared device.

CONCLUSION

The modified SPECTRALIS is a device modification to the cleared SPECTRALIS predicate device. The modified SPECTRALIS has the same Intended Use/Indications for Use and the same fundamental scientific technology as the cleared SPECTRALIS predicate device.

In summary, Heidelberg Engineering GmbH is of the opinion that the modified SPECTRALIS HRA+OCT and variants, does not introduce any new potential safety risks, is as effective as the cleared SPECTRALIS HRA+OCT and variants and concludes that the modified SPECTRALIS HRA+OCT and variants, is substantially equivalent to the predicate device.

This 510(k) summary for the Heidelberg Engineering SPECTRALIS HRA+OCT and variants is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR§807.92.