October 18, 2018

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

Re: K182569
Trade/Device Name: Spectralis HRA+OCT and variants with High Magnification Module
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO, MYC
Dated: September 17, 2018
Received: September 18, 2018

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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 yours,

Bradley S. Cunningham -A

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)*
K182569

Device Name
SPECTRALIS HRA+OCT and variants with High Magnification Module

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 imaging
- fluorescence imaging (fluorescein angiography, indocyanine green angiography; SPECTRALIS HRA+OCT, SPECTRALIS HRA)
- autofluorescence imaging (SPECTRALIS HRA+OCT, SPECTRALIS HRA and SPECTRALIS OCT with BluePeak)
- performing 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

The device is indicated for viewing geographic atrophy.

The SPECTRALIS OCT Angiography Module is indicated as an aid in the visualization of vascular structures of the retina and choroid.

The SPECTRALIS HRA+OCT and SPECTRALIS OCT include the following reference databases:
- a retinal nerve fiber layer thickness reference database, which is used to quantitatively compare the retinal nerve fiber layer in the human retina to values of Caucasian normal subjects – the classification result being valid only for Caucasian subjects
- a reference database for retinal nerve fiber layer thickness and optic nerve head neuroretinal rim parameter measurements, which is used to quantitatively compare the retinal nerve fiber layer and neuroretinal rim in the human retina to values of normal subjects of different races and ethnicities representing the population mix of the USA (Glaucoma Module Premium Edition)

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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K182569 510(K) SUMMARY

Date Prepared September 26, 2018

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COMMON/USUAL NAME

Optical Coherence Tomography

PROPRIETARY OR TRADE NAMES

SPECTRALIS HRA+OCT with High Magnification Module

CLASSIFICATION INFORMATION

Classification Name:	Tomography, Optical Coherence 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 with OCT Angiography Module
Applicant:	Heidelberg Engineering GmbH
510(k) Premarket Notification number:	K181594
Classification:	Class II
CFR Title:	21 CFR 886.1570
FDA Product Code(s):	OBO, MYC
Classification Name:	Tomography, Optical Coherence Ophthalmoscope, Laser, Scanning
Common Name:	Optical Coherence Tomography
Medical Specialty:	Ophthalmic
Classification Panel:	Ophthalmic Device Panel

GENERAL DEVICE DESCRIPTION

The Heidelberg Engineering SPECTRALIS HRA+OCT is a device used to image the anterior and posterior segments of the human eye. The SPECTRALIS HRA+OCT is a combination of a confocal laser-scanning ophthalmoscope (cSLO, the HRA portion) and a spectral-domain optical coherence tomographer (SD-OCT). The confocal laser-scanning part of the device allows for acquisition of reflectance images (with blue, green or infrared light), conventional angiography images (using fluorescein or indocyanine green dye) and autofluorescence images. The different imaging modes can be used either alone or simultaneously. The SD-OCT part of the device acquires cross-sectional and volume images, together with an HRA cSLO image.

A blue laser is used for fluorescein angiography, autofluorescence imaging, and blue reflectance imaging, and two infrared lasers are used for indocyanine green angiography and infrared reflectance imaging. A green laser is used for MultiColor imaging (“composite color images”). MultiColor imaging is the simultaneous acquisition of infrared, green and blue reflectance images that can be viewed separately or as a composite color image. For SD-OCT imaging, an infrared super-luminescent diode and a spectral interferometer are used to create the cross-sectional images.

The purpose of this premarket notification [510(k)] is to add the High Magnification Module (HMM) as an optional, exchangeable accessory objective lens to the SPECTRALIS HRA+OCT.

The HMM is offering an 8° field of view (FOV) and allows for cSLO imaging only. It offers a magnified view of parts of the retina with improved resolution. Compared to

the standard objective with 30° FOV, it has an approximately 4 times increased digital resolution, with optical resolution approximately 25% improved compared to the standard objective. With the new HMM objective, the digital resolution for a FOV of 8° is 1536x1536 pixels for High Resolution imaging, and 768x768 pixels for High Speed imaging. The functionality for averaging images with the proprietary automatic real-time (ART) eye tracking is still maintained.

cSLO imaging with the HMM is only intended for qualitative use.

- No quantitative automatic measurements are performed on HMM images.
- No classifications against reference data are performed on HMM images

Besides the addition of the optional High Magnification Module, the SPECTRALIS device is unchanged.

INDICATIONS FOR USE – SPECTRALIS PREDICATE DEVICE

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 imaging
- fluorescence imaging (fluorescein angiography, indocyanine green angiography; SPECTRALIS HRA+OCT, SPECTRALIS HRA)
- autofluorescence imaging (SPECTRALIS HRA+OCT, SPECTRALIS HRA and SPECTRALIS OCT with BluePeak)
- performing 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

The device is indicated for viewing geographic atrophy.
The SPECTRALIS OCT Angiography Module is indicated as an aid in the visualization of vascular structures of the retina and choroid.
The SPECTRALIS HRA+OCT and SPECTRALIS OCT include the following reference databases:

- a retinal nerve fiber layer thickness reference database, which is used to quantitatively compare the retinal nerve fiber layer in the human retina to values of Caucasian normal subjects – the classification result being valid only for Caucasian subjects
- a reference database for retinal nerve fiber layer thickness and optic nerve head neuroretinal rim parameter measurements, which is used to quantitatively compare the retinal nerve fiber layer and neuroretinal rim in the human retina to values of normal subjects of different races and ethnicities representing the population mix of the USA (Glaucoma Module Premium Edition)

INDICATIONS FOR USE – MODIFIED SPECTRALIS

The Indications for Use for the modified SPECTRALIS is identical to the Indications for Use of the cleared SPECTRALIS predicate device.

SUBSTANTIAL EQUIVALENCE

The modified SPECTRALIS HRA+OCT with High Magnification Module is a device modification to the cleared SPECTRALIS HRA+OCT and variants (K181594) predicate device. Technological detail characteristics of the device are unchanged except for the modification as stated in the General Device Description. The modified SPECTRALIS has the same Indications for Use and maintains 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 in K181594. The changes applied to the SPECTRALIS since the clearance in K181594 do not change the intended patient populations, the type of acquired images, or how the SPECTRALIS may be used as an aid to clinical evaluation.

Non-clinical performance testing was conducted on the modified SPECTRALIS HRA+OCT to verify that the device is safe and effective for its intended use and indications for use.

The modification to the device does not raise issues of safety and effectiveness. A comparison of technological characteristics and non-clinical performance testing demonstrate that the SPECTRALIS device is substantially equivalent to the unmodified predicate device.

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

INDICATIONS FOR USE STATEMENT CHART

K181594 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 imaging • fluorescence imaging (fluorescein angiography, indocyanine green angiography; SPECTRALIS HRA+OCT, SPECTRALIS HRA) • autofluorescence imaging (SPECTRALIS HRA+OCT, SPECTRALIS HRA and SPECTRALIS OCT with BluePeak) • performing 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 The device is indicated for viewing geographic atrophy. The SPECTRALIS OCT Angiography Module is indicated as an aid in the visualization of vascular structures of the retina and choroid. The SPECTRALIS HRA+OCT and SPECTRALIS OCT include the following reference databases: • a retinal nerve fiber layer thickness reference database, which is used to quantitatively compare the retinal nerve fiber layer in the human retina to values of Caucasian normal subjects – the classification result being valid only for Caucasian subjects • a reference database for retinal nerve fiber layer thickness and optic nerve head neuroretinal rim parameter measurements, which is used to quantitatively compare the retinal nerve fiber layer and neuroretinal rim in the human retina to values of normal subjects of different races and ethnicities representing the population mix of the USA (Glaucoma Module Premium Edition)	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 imaging • fluorescence imaging (fluorescein angiography, indocyanine green angiography; SPECTRALIS HRA+OCT, SPECTRALIS HRA) • autofluorescence imaging (SPECTRALIS HRA+OCT, SPECTRALIS HRA and SPECTRALIS OCT with BluePeak) • performing 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 The device is indicated for viewing geographic atrophy. The SPECTRALIS OCT Angiography Module is indicated as an aid in the visualization of vascular structures of the retina and choroid. The SPECTRALIS HRA+OCT and SPECTRALIS OCT include the following reference databases: • a retinal nerve fiber layer thickness reference database, which is used to quantitatively compare the retinal nerve fiber layer in the human retina to values of Caucasian normal subjects – the classification result being valid only for Caucasian subjects • a reference database for retinal nerve fiber layer thickness and optic nerve head neuroretinal rim parameter measurements, which is used to quantitatively compare the retinal nerve fiber layer and neuroretinal rim in the human retina to values of normal subjects of different races and ethnicities representing the population mix of the USA (Glaucoma Module Premium Edition)	Same

TECHNOLOGICAL CHARACTERISTICS COMPARISON CHART

	PREDICATE DEVICE K181594 SPECTRALIS HRA+OCT	SUBJECT DEVICE	Discussion
Device classification name	Optical Coherence Tomographer (OCT)	Optical Coherence Tomographer (OCT)	Same
Technology and optical setup	Confocal Scanning Laser Ophthalmoscope (SLO) and Spectral-Domain Optical Coherence Tomograph (OCT)	Confocal Scanning Laser Ophthalmoscope (SLO) and Spectral-Domain Optical Coherence Tomograph (OCT)	Same
Lights sources and wavelength of light emitted	• Near infrared reflectance images: diode laser, 815 nm, • Blue light reflectance images: diode laser, 486 nm, or optically pumped semiconductor laser, 488 nm • Green light reflectance images: diode laser, 518 nm • Fluorescein angiography: diode laser, 486 nm, or optically pumped semiconductor laser, 488 nm • Indocyanine green angiography: diode laser, 786 nm • Optical coherence tomography: superluminescence diode, 840 nm to 920 nm (weighted average 880 nm)	• Near infrared reflectance images: diode laser, 815 nm, • Blue light reflectance images: diode laser, 486 nm, or optically pumped semiconductor laser, 488 nm • Green light reflectance images: diode laser, 518 nm • Fluorescein angiography: diode laser, 486 nm, or optically pumped semiconductor laser, 488 nm • Indocyanine green angiography: diode laser, 786 nm Optical coherence tomography: superluminescence diode, 840 nm to 920 nm (weighted average 880 nm)	Same
Amount of light irradiated to retina (exposure)	Low amount, does not exceed Class I laser accessible emission limits	Low amount, does not exceed Class I laser accessible emission limits	Same
Lateral field of view (SLO)	SO (standard objective): 15° x 15° to 30° x 30° WFO/WFO2: 25° x 25° to Ø 55° UWF Objective: 51° x 51° to Ø 102°	SO (standard objective): 15° x 15° to 30° x 30° HMM: 8° WFO/WFO2: 25° x 25° to Ø 55° UWF Objective: 51° x 51° to Ø 102°	Different; introduction of HMM

	PREDICATE DEVICE K181594 SPECTRALIS HRA+OCT	SUBJECT DEVICE	Discussion
Lateral digital resolution (SLO)	high speed mode: 11 µm (SO) to 40 µm (UWF) high resolution mode: 6 µm (SO) to 20 µm (UWF)	high speed mode: 3µm (HMM), 11 µm (SO) to 40 µm (UWF) high resolution mode: 1.5µm (HMM), 6 µm (SO) to 20 µm (UWF)	Different; increased digital resolution with HMM
Digital image size (SLO)	High Speed mode: 384x384 pixels to 768x768 pixels High Resolution mode: 768x768 to 1536 x 1536 pixels	High Speed mode: 384x384 pixels to 768x768 pixels; (with HMM: 768x768 pixels only) High Resolution mode: 768x768 to 1536 x 1536 pixels; (with HMM: 1536 x 1536 pixels only)	Different; only one image size available for HMM
Standard Objective Lens	19.5 mm working distance, 31 mm length, 49 outer mm diameter	19.5 mm working distance, 31 mm length, 49 outer mm diameter	Same
High Magnification Module (HMM)	not available	50mm working distance, 29mm length, 49mm outer diameter; not used for measurements;	Different; introduction of HMM
Anterior Segment Module (ASM) Objective Lens	12 mm working distance, 65 mm length, 49.5 mm outer diameter 30° field of view not used for measurements	12 mm working distance, 65 mm length, 49.5 mm outer diameter 30° field of view not used for measurements	Same
Wide Field Objective (WFO) and WFO2	10 mm working distance, 46 mm length, 49 mm outer diameter; 55° field of view; not used for measurements; WFO2 has the same design and optical layout as WFO, but an improved anti-reflective coating	10 mm working distance, 46 mm length, 49 mm outer diameter; 55° field of view; not used for measurements; WFO2 has the same design and optical layout as WFO, but an improved anti-reflective coating	Same
Ultra-Widefield (UWF) Accessory Objective Lens	7.8 mm working distance, 167 mm length, 80 mm outer diameter; 102° field of view; not used for measurements	7.8 mm working distance, 167 mm length, 80 mm outer diameter; 102° field of view; not used for measurements	Same

The imaging parameters, which characterize the field of view, scaling, lateral resolution, and image quality of the HMM were evaluated by simulation (ray tracing) and could be verified experimentally. Whenever it was possible, reasonable acceptance criteria were predefined and the values were compared to the 30° standard objective. All the relevant optical parameters of the HMM are in very good agreement with the theoretical values, resulting by ray tracing. Additionally, it could be shown that the image quality of the HMM is comparable to the SO regarding illumination homogeneity and structure sharpness. For all verification tests, the predefined acceptance criteria were fulfilled, showing that the device with HMM is as safe and effective as the unmodified device.

The 30° standard objective is still delivered with all the Spectralis units and is not intended to be replaced as standard imaging objective by HMM imaging. A snap-in bayonet mount allows for fast and easy exchange of the objectives in case where a higher lateral resolution (and smaller field of view) seems to be favorable (HMM), or a standard field of view is advantageous (SO).

NON-CLINICAL PERFORMANCE TESTING

The modified SPECTRALIS was evaluated according to the requirements of FDA recognized consensus standards:

- ISO 14971: Medical Devices - Application of Risk Management to Medical Devices,
- AAMI / ANSI ES60601-1:2005 Edition 3.1: Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance,
- IEC 60825-1 Edition 2.0 2007-03: Safety of Laser Products - Part 1: Equipment Classification, And Requirements,
- AAMI / ANSI / IEC 62304:2006: Medical Device Software - Software Life Cycle Processes, and
- ANSI AAMI IEC 62366-1:2015: Medical devices - Part 1: Application of usability engineering to medical devices

and was found to meet the requirements of the applicable parts.

Biocompatibility and electromagnetic compatibility testing was conducted on the previously cleared SPECTRALIS HRA+OCT device. Applicable parts are unchanged for the addition of the HMM in raw materials, design, manufacturing, and material processing since their last clearance and therefore repeated tests were not required for the addition of the HMM.

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 13485:2016. 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.

Heidelberg Engineering performed bench testing – including risk mitigation measures, field of view, image geometry, lateral resolution, and image quality assessment– and software verification and validation, to confirm that the modified SPECTRALIS HRA+OCT functions equivalently to the predicate SPECTRALIS HRA+OCT.

CONCLUSION

Comparison of technological characteristics and evaluation of non-clinical performance testing show that the modifications to the SPECTRALIS HRA+OCT and variants do not introduce any new potential safety risk and the device is as safe and effective as the predicate devices, therefore supporting a determination of substantial equivalence.