September 9, 2020

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

Re: K201252
Trade/Device Name: Spectralis HRA+OCT and variants
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO, MYC
Dated: June 10, 2020
Received: June 11, 2020

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/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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201252

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 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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510(K) SUMMARY

Date Prepared August 18, 2020

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COMMON/USUAL NAME

Optical Coherence Tomography

PROPRIETARY OR TRADE NAMES

SPECTRALIS HRA+OCT and variants

CLASSIFICATION INFORMATION

Regulation Number:	21 CFR 886.1570
Classification name:	Ophthalmoscope
Device Class:	II
Common name:	Optical Coherence Tomography
Product Codes, Name:	OBO (Tomography, Optical Coherence)
	MYC (Ophthalmoscope, Laser, Scanning)
Medical Specialty:	Ophthalmic
Classification Panel:	Ophthalmic Device Panel

LEGALLY MARKETED UNMODIFIED PREDICATE DEVICE

Trade/Device Name:	SPECTRALIS HRA+OCT and variants
Applicant:	Heidelberg Engineering GmbH
510(k) Premarket Notification number:	K192391
Classification:	Class II
Regulation Number:	21 CFR 886.1570
Product Codes, Name:	OBO (Tomography, Optical Coherence) MYC (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.

DEVICE MODIFICATIONS

The purpose of this premarket notification [510(k)] is to modify the SPECTRALIS HRA+OCT with the updated camera head and OCT controller, the additional OCT scan mode, and predefined OCTA scan pattern.

The following changes have been applied to the device:

- Camera head hardware update
  - Modified beam splitter coating to allow for more light in the OCT reference arm
  - Improved OCT scanner controller

- Enhanced Vitreous Imaging OCT acquisition mode
- Additional predefined scan patterns
    - OCT Angiography Scout scan: A fast overview OCTA scan
    - OCT Angiography Dense ART (DART) scans: Narrow OCTA B-scans with flow overlay

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

INDICATIONS FOR USE STATEMENT CHART

K192391 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 K192391 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
Accessory objective lenses (besides Standard Objective)	Anterior Segment Module (ASM) Wide Field Objective (WFO) Ultra Widefield Objective (UWF) High Magnification Module (HMM)	Anterior Segment Module (ASM) Wide Field Objective (WFO) Ultra Widefield Objective (UWF) High Magnification Module (HMM)	Same

	PREDICATE DEVICE K192391 SPECTRALIS HRA+OCT	SUBJECT DEVICE	Discussion
Lateral field of view (SLO)	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°	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°	Same
Lateral digital resolution (SLO)	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)	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)	Same
Lateral optical resolution (OCT)	14 µm (standard objective) 24 µm (WFO/WFO2)	14 µm (standard objective) 24 µm (WFO/WFO2)	Same
Optical depth resolution (OCT)	7 µm	7 µm	Same
Digital image size (SLO)	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)	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)	Same
OCT acquisition speed (Maximum A-scan rate)	40 kHz (Firewire) 85 kHz (Thunderbolt)	40 kHz (Firewire) 85 kHz (Thunderbolt)	Same
OCT Scanner Controller	Standard controller	Updated controller	Different; the updated controller reduces scanner non-linearity, repositioning error and settle times

	PREDICATE DEVICE K192391 SPECTRALIS HRA+OCT	SUBJECT DEVICE	Discussion
OCT Beam Splitter	Standard coating	Modified coating	Different; coating modified to allow more light to the reference arm
OCT imaging modes	Standard Enhanced Depth Imaging (EDI)	Standard Enhanced Depth Imaging (EDI) Enhanced Vitreous Imaging (EVI)	Different: Addition of EVI mode
OCTA scan types	Volume	Volume OCTA Scout OCTA DART Volume OCTA DART Line	Different: Additional predefined OCTA scan pattern

SUBSTANTIAL EQUIVALENCE DISCUSSION

The modified SPECTRALIS HRA+OCT is a device modification to the cleared SPECTRALIS HRA+OCT and variants (K192391) predicate device. Technological detail characteristics of the device are unchanged except for the modification as stated above. The modified SPECTRALIS has the same Indications for Use and maintains the same fundamental scientific technology as the predicate device.

The modified SPECTRALIS HRA+OCT and variants measures the same ophthalmic features as the cleared SPECTRALIS HRA+OCT in K192391. The changes applied to the SPECTRALIS since the clearance in K192391 do not change the intended patient populations, the type of acquired images, or that the SPECTRALIS may be used as an aid to clinical evaluation.

The light sources integrated into the modified device are the same as the predicate (unmodified) device. The modification of the OCT beam splitter coating to the predicate (unmodified) device does not alter the optical pathway, nor does it change the patient light exposure.

The addition of additional scan patterns, updated OCT scanner controller, and of Enhanced Vitreous Imaging mode, do not change the basic scientific technology of the predicate (unmodified) device.

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 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 60601-1-2 Edition 4.0 2014-02, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests,
- IEC 62304 Edition 1.1 2015-06: Medical Device Software - Software Life Cycle Processes,

and was found to meet the requirements of the applicable parts, demonstrating that the safety and efficacy of the modified device is comparable to the predicate.

Heidelberg Engineering performed bench testing including bench testing of OCT imaging properties, validation and verification activities, and ongoing quality control, to confirm that the modified SPECTRALIS HRA+OCT functions equivalently to the predicate SPECTRALIS HRA+OCT.

The modifications to the device do 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.

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.