September 26, 2019

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

Re: K192391
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: August 30, 2019
Received: September 3, 2019

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,

Tieuvi Nguyen, Ph.D.
Director (Acting)
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)*
K192391

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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# 510(K) SUMMARY

Date Prepared: September 18, 2019

## SPONSOR/510(K) OWNER/ MANUFACTURER

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## OFFICIAL CONTACT PERSON

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## COMMON/USUAL NAME

Optical Coherence Tomography

## PROPRIETARY OR TRADE NAMES

SPECTRALIS HRA+OCT and variants

## CLASSIFICATION INFORMATION

| | |
|---|---|
| Classification Name: | Tomography, Optical Coherence<br>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: | K182569 |
| Classification: | Class II |
| CFR Title: | 21 CFR 886.1570 |
| FDA Product Code(s): | OBO, MYC |
| Classification Name: | Tomography, Optical Coherence<br>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.

Because of discontinuation of device components, the following changes have been applied to the device:

- Replacement of the OCT line camera in the spectrometer with an equivalent camera from the same manufacturer, and comparable specifications;
- Update of the digital device interface from Thunderbolt to Thunderbolt 2;
    - With the update of the TDI, the device complies with electromagnetic compatibility standard IEC 60601-1-2 Edition 4.0.

The modified device with the updated components will replace the cleared device (K182569) with OCT2 module (Thunderbolt). Manufacturing of the device with FireWire interface will soon be discontinued.

The purpose of this premarket notification [510(k)] is to modify the SPECTRALIS HRA+OCT with the updated OCT line camera and digital device interface.

Besides the updated hardware, 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.

## 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 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,
- AAMI / ANSI / IEC 62304:2006: Medical Device Software - Software Life Cycle Processes, and

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.

## 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 electrical safety testing, EMC testing, 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.

## SUBSTANTIAL EQUIVALENCE

The modified SPECTRALIS HRA+OCT is a device modification to the cleared SPECTRALIS HRA+OCT and variants (K182569) 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.

## INDICATIONS FOR USE STATEMENT CHART

| K182569 PREDICATE DEVICE | SUBJECT DEVICE | Same or Different |
|---|---|---|
| The SPECTRALIS is a non-contact ophthalmic diagnostic imaging device. It is intended for:<br>• viewing the posterior segment of the eye, including two- and three-dimensional imaging<br>• cross-sectional imaging (SPECTRALIS HRA+OCT and SPECTRALIS OCT)<br>• fundus imaging<br>• fluorescence imaging (fluorescein angiography, indocyanine green angiography; SPECTRALIS HRA+OCT, SPECTRALIS HRA)<br>• autofluorescence imaging (SPECTRALIS HRA+OCT, SPECTRALIS HRA and SPECTRALIS OCT with BluePeak)<br>• performing measurements of ocular anatomy and ocular lesions.<br>The device is indicated as an aid in the detection and management of various ocular diseases, including:<br>• age-related macular degeneration<br>• macular edema<br>• diabetic retinopathy<br>• retinal and choroidal vascular diseases<br>• glaucoma<br>The device is indicated for viewing geographic atrophy.<br>The SPECTRALIS OCT Angiography Module is indicated as an aid in the visualization of vascular structures of the retina and choroid.<br>The SPECTRALIS HRA+OCT and SPECTRALIS OCT include the following reference databases:<br>• a retinal nerve fiber layer thickness reference database, which is used to quantitatively compare the retinal nerve fiber layer in the | The SPECTRALIS is a non-contact ophthalmic diagnostic imaging device. It is intended for:<br>• viewing the posterior segment of the eye, including two- and three-dimensional imaging<br>• cross-sectional imaging (SPECTRALIS HRA+OCT and SPECTRALIS OCT)<br>• fundus imaging<br>• fluorescence imaging (fluorescein angiography, indocyanine green angiography; SPECTRALIS HRA+OCT, SPECTRALIS HRA)<br>• autofluorescence imaging (SPECTRALIS HRA+OCT, SPECTRALIS HRA and SPECTRALIS OCT with BluePeak)<br>• performing measurements of ocular anatomy and ocular lesions.<br>The device is indicated as an aid in the detection and management of various ocular diseases, including:<br>• age-related macular degeneration<br>• macular edema<br>• diabetic retinopathy<br>• retinal and choroidal vascular diseases<br>• glaucoma<br>The device is indicated for viewing geographic atrophy.<br>The SPECTRALIS OCT Angiography Module is indicated as an aid in the visualization of vascular structures of the retina and choroid.<br>The SPECTRALIS HRA+OCT and SPECTRALIS OCT include the following reference databases:<br>• a retinal nerve fiber layer thickness reference database, which is used to quantitatively compare the retinal nerve fiber layer in the | Same |

| K182569 PREDICATE DEVICE | SUBJECT DEVICE | Same or Different |
|---|---|---|
| human retina to values of Caucasian normal subjects – the classification result being valid only for Caucasian subjects<br>• 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) | human retina to values of Caucasian normal subjects – the classification result being valid only for Caucasian subjects<br>• 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) | |

## TECHNOLOGICAL CHARACTERISTICS COMPARISON CHART

| | PREDICATE DEVICE K182569 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,<br>• Blue light reflectance images: diode laser, 486 nm, or optically pumped semiconductor laser, 488 nm<br>• Green light reflectance images: diode laser, 518 nm<br>• Fluorescein angiography: diode laser, 486 nm, or optically pumped semiconductor laser, 488 nm<br>• Indocyanine green angiography: diode laser, 786 nm<br>• Optical coherence tomography: superluminescence diode, 840 nm to 920 nm (weighted average 880 nm) | • Near infrared reflectance images: diode laser, 815 nm,<br>• Blue light reflectance images: diode laser, 486 nm, or optically pumped semiconductor laser, 488 nm<br>• Green light reflectance images: diode laser, 518 nm<br>• Fluorescein angiography: diode laser, 486 nm, or optically pumped semiconductor laser, 488 nm<br>• Indocyanine green angiography: diode laser, 786 nm<br>• 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)<br>Wide Field Objective (WFO)<br>Ultra Widefield Objective (UWF)<br>High Magnification Module (HMM) | Anterior Segment Module (ASM)<br>Wide Field Objective (WFO)<br>Ultra Widefield Objective (UWF)<br>High Magnification Module (HMM) | Same |

| | PREDICATE DEVICE K182569 SPECTRALIS HRA+OCT | SUBJECT DEVICE | Discussion |
|---|---|---|---|
| Lateral field of view (SLO) | SO (standard objective):<br>15° x 15° to 30° x 30°<br>HMM:<br>8°<br>WFO/WFO2:<br>25° x 25° to Ø 55°<br>UWF Objective:<br>51° x 51° to Ø 102° | SO (standard objective):<br>15° x 15° to 30° x 30°<br>HMM:<br>8°<br>WFO/WFO2:<br>25° x 25° to Ø 55°<br>UWF Objective:<br>51° x 51° to Ø 102° | Same |
| Lateral digital resolution (SLO) | high speed mode: 3µm (HMM), 11 µm (SO) to 40 µm (UWF)<br>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)<br>high resolution mode: 1.5µm (HMM), 6 µm (SO) to 20 µm (UWF) | Same |
| Digital image size (SLO) | High Speed mode: 384x384 pixels to 768x768 pixels; (with HMM: 768x768 pixels only)<br>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)<br>High Resolution mode: 768x768 to 1536 x 1536 pixels; (with HMM: 1536 x 1536 pixels only) | Same |
| Digital device interface | FireWire (OCT(1) module)<br>Thunderbolt (OCT2 module) | Thunderbolt 2 | Different; the Firewire device will be discontinued; device interface updated to Thunderbolt 2 |
| OCT acquisition speed (Maximum A-scan rate) | 40 kHz (OCT(1) module)<br>85 kHz (OCT2 module) | 85 kHz | Different; the Firewire device will be discontinued; |
| Lateral optical resolution (OCT) | 14 µm (standard objective)<br>24 µm (WFO/WFO2) | 14 µm (standard objective)<br>24 µm (WFO/WFO2) | Same |
| Optical depth resolution (OCT) | 7 µm | 7 µm | Same |

The modified SPECTRALIS HRA+OCT and variants measures the same ophthalmic features and parameters as the cleared SPECTRALIS HRA+OCT in K182569. The changes applied to the SPECTRALIS since the clearance in K182569 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 following performance testing was conducted:

| Test | Verification / Validation Method(s) | Acceptance Criteria | Summary of Results |
|---|---|---|---|
| **Electrical Safety** | According to AAMI / ANSI ES60601-1:2005 Edition 3.1 | According to AAMI / ANSI ES60601-1:2005 Edition 3.1 | All tests passed, and the device was found to comply |
| **Electromagnetic Compatibility** | According to IEC 60601-1-2 Edition 4.0 | According to IEC 60601-1-2 Edition 4.0 | All tests passed, and the device was found to comply |
| **Laser Safety Analysis** | According to IEC 60825-1:2007 | According to IEC 60825-1:2007 | The total accessible emission under all circumstances is below the accessible emission limit for a Class I laser product. |
| **System and software validation and verification** | According to 21 CFR 820.30 and AAMI / ANSI / IEC 62304:2006 | According to 21 CFR 820.30 and AAMI / ANSI / IEC 62304:2006 | All tests passed, and the device performed according to the requirements |
| **Bench testing: OCT Sensitivity** | Quantification of absolute SNR | Sensitivity ≥ 95 dB, with variation < 2dB | Pass for both criteria |
| **Bench testing: OCT Signal Rolloff** | Quantification of SNR as a function of reference arm length | Decay in absolute sensitivity ≤ 5 dB for an increase in reference arm length of 1.6 mm | Rolloff ≈ 2 dB/mm, thus passed |

Non-clinical performance test results were compared to the results of the predicate device and showed that the modified device is functionally equivalent to the predicate device, and is as safe and efficient as the predicate device.

Risk assessment was conducted on the modified SPECTRALIS, and the impact of the design modifications were assessed on the predicate 510(k) cleared device. There were no newly identified risks due to the modification.

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.