August 30, 2018

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

Re: K173648
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: May 30, 2018
Received: June 1, 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,

Alexander Beylin -S
2018.08.30 13:12:03 -04'00'

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)*
K173648

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 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 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 June 12, 2018

## SPONSOR/510(K) OWNER/ MANUFACTURER

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Establishment Registration No.: 8043762

## 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: | Ophthalmoscope, AC Powered<br>Ophthalmoscope, Laser, Scanning |
| Medical Specialty: | Ophthalmic |
| Device Class: | II |
| Classification Panel: | Ophthalmic Device Panel |
| Product Codes: | OBO, MYC |

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## 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: | K172649 |
| Classification: | Class II |
| CFR Title: | 21 CFR 886.1570 |
| FDA Product Code(s): | OBO, MYC |
| Classification Name: | Ophthalmoscope, AC Powered<br>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. In K172649, an updated 55° objective lens (WFO2) with enhanced anti-reflective coating was added to allow for Widefield MultiColor imaging, as well as an updated and faster spectrometer, called OCT2 module, a replacement of the patient and data management system, named Heyex 2, restructured user documentation, and Windows 10 support.

The modification to the SPECTRALIS is:

Widefield OCT – In addition to OCT imaging with the standard objective (for posterior segment imaging; 30° field of view) and the Anterior Segment Objective

(anterior segment imaging; 30° field of view), OCT imaging is enabled with the Wide Field Objective (WFO) and Wide Field Objective 2 (WFO2). Both objectives provide a 55° diameter circular field of view. The field of view can be reduced by software to 35° and 25°. The only difference between WFO and WFO2 is an enhanced anti-reflective coating to allow for MultiColor imaging on the WFO2 (cleared in K172649). Both coatings cover the OCT wavelength, so OCT imaging can be enabled for both objective lenses.

## 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 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.

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## INDICATIONS FOR USE – MODIFIED SPECTRALIS

The Indications for Use for the modified SPECTRALIS is only slightly modified to the Indications for Use of the cleared SPECTRALIS predicate device for clarification. The modified Indication for Use statement is:

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 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 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)

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## SUBSTANTIAL EQUIVALENCE

The modified SPECTRALIS HRA+OCT and variants is a device modification to the cleared SPECTRALIS HRA+OCT and variants (K172649) predicate device. The modified SPECTRALIS has a slightly modified 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 K172649.

The changes applied to the SPECTRALIS since the clearance in K172649 do not change the subject population for whom the device is used, the type of images to be acquired, the disease or condition to be diagnosed, 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.

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INTENDED USE/INDICATIONS FOR USE STATEMENT CHART

| K172649 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:<br>• viewing the posterior segment of the eye, including two- and three-dimensional 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><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><br>The device is indicated for viewing geographic atrophy.<br><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 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 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 Indications for Use statement has been updated for clarification:<br><br>1.) Formatting for improved readability<br><br>2.) “fundus photography” changed to “fundus imaging” for clarity<br><br>3.) Removed statement related to neuro-degenerative diseases upon FDA request, to not imply the use of the device to diagnose neurological based diseases/ conditions.<br><br>4.) Clarification on RDBs included in the device |

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INTENDED USE CHARACTERISTICS CHART

| | PREDICATE DEVICE K172649 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/WFO2, or UWF objective lens | Yes, using standard, WFO/WFO2, or UWF objective lens | Same |
| Images of anterior segment of eye | With Anterior Segment Module (K113129) | With Anterior Segment Module (K113129) | Same |
| OCT imaging of the anterior and posterior segment | Anterior segment: With Anterior Segment Module (K113129)<br>Posterior Segment:<br>30° OCT field of view with standard objective | Anterior segment: With Anterior Segment Module (K113129)<br>Posterior Segment:<br>30° OCT field of view with standard objective, 55° OCT field of view with WFO/WFO2 | Different; optional OCT imaging with WFO/WFO2 was introduced |
| RNFL Reference Database | RNFL thickness in reference database for 12° circle scans (K101223)<br>RNFL thickness in reference database for fixed diameter circle scans (K152205) | RNFL thickness in reference database for 12° circle scans (K101223)<br>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.

Heidelberg Engineering performed bench testing – including light safety, image geometry, 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.

## OPTICAL RESOLUTION TESTING

Bench testing was performed in order to assess all the relevant system properties (resolution, scaling, image quality etc.) for the WFO lens. In particular, a 1951 USAF resolution test chart (MIL-STD-150A) was used to objectively quantify the loss of optical lateral resolution comparing wide-field OCT scans with standard objective (SO) OCT patterns.

The bench testing resulted in an average value of 13µm for the SO, and of 18µm for the WFO. Compared to the standard lens, the WFO causes a loss in optical lateral resolution of about 3 resolution elements on a USAF 1951 resolution target. These values are in agreement with the theoretical evaluation.

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## CONCLUSION

The modified SPECTRALIS is a device modification to the cleared SPECTRALIS predicate device. The modified SPECTRALIS has a slightly modified 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.