October 20, 2023

Heidelberg Engineering GmbH
℅ Lena Sattler
Consultant
Orasi Consulting, LLC.
226 1st Street
Bonita Springs, Florida 34134

Re: K223557
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: September 15, 2023
Received: September 15, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Y. Ng -S

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)*
K223557

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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HEIDELBERG ENGINEERING

510(K) SUMMARY

Date Prepared October 20, 2023

SPONSOR/510(K) OWNER/ MANUFACTURER

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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 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

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PREDICATE DEVICE

SPECTRALIS HRA+OCT and variants (K201252), Heidelberg Engineering GmbH

INDICATIONS FOR USE

The SPECTRALIS is a non-contact ophthalmic diagnostic imaging device. It is intended for:

- viewing the posterior segment of the eye, including two- and three-dimensional imaging
- cross-sectional imaging (SPECTRALIS HRA+OCT and SPECTRALIS OCT)
- fundus 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)

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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 following changes have been applied to the device subject of this 510(k):

- Widefield Reflectance mode for artifacts suppression
- Regression analysis in Glaucoma Module Premium Edition
- Thunderbolt 3 interface
- Thunderbolt cable fan
- Process separation of acquisition software module
- Windows 11 Support

COMPARISON BETWEEN THE SUBJECT AND THE PREDICATE DEVICE

The modified SPECTRALIS HRA+OCT is a device modification to the cleared SPECTRALIS HRA+OCT and variants (K201252) 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.

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INDICATIONS FOR USE STATEMENT CHART

K221252 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

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TECHNOLOGICAL CHARACTERISTICS COMPARISON CHART

	PREDICATE DEVICE K201252 SPECTRALIS HRA+OCT	**SUBJECT DEVICE**	**Same or Different**
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
Physical Dimensions	• Laser scanning camera: 235 mm x 100 mm x 205 mm • Instrumentation Mount (KT): 470 mm x 325 mm x 550 mm • Power supply including spectrometer: 180 mm x 335 mm x 165 mm Operation panel: 170 mm x 185 mm x 100 mm	• Laser scanning camera: 235 mm x 100 mm x 205 mm • Instrumentation Mount (KT): 470 mm x 325 mm x 550 mm • Power supply including spectrometer: 180 mm x 335 mm x 165 mm • Operation panel: 170 mm x 185 mm x 100 mm	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
Wavelength of light detected	• Near infrared reflectance images: 815 nm • Blue light reflectance images: 486-488 nm • Green light reflectance images: 518 nm • Fluorescein angiography: 500 nm to 720 nm • Indocyanine green angiography: 800 nm to 900 nm • Optical coherence tomography: 840nm to 920 nm	• Near infrared reflectance images: 815 nm • Blue light reflectance images: 486-488 nm • Green light reflectance images: 518 nm • Fluorescein angiography: 500 nm to 720 nm • Indocyanine green angiography: 800 nm to 900 nm • Optical coherence tomography: 840 nm to 920 nm	Same

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Type of light source used	Laser diodes (LD) and superluminescence diode (SLD)	Laser diodes (LD) and superluminescence diode (SLD)	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 optical resolution (OCT)	14 µm (standard objective) 24 µm (WFO2)	14 µm (standard objective) 24 µm (WFO2)	Same
Focus adjustment range	Correction of patient's refractive errors: minimum range: -12 to +12 diopters	Correction of patient's refractive errors: minimum range: -12 to +12 diopters	Same
Optical depth resolution (OCT)	7 µm	7 µm	Same
OCT acquisition speed (Maximum A-scan rate)	40 kHz (Firewire) 85 kHz (Thunderbolt) Has possibility for higher speeds (*future submission*)	40 kHz (Firewire) 85 kHz (Thunderbolt) Has possibility for higher speeds (*future submission*)	Same
OCT acquisition modes	Standard Enhanced Depth Imaging (EDI) Enhanced Vitreous Imaging (EVI)	Standard Enhanced Depth Imaging (EDI) Enhanced Vitreous Imaging (EVI)	Same
cSLO imaging modes for artifact suppression	Reflectance (R) Cross-Polarization (XP)	Reflectance (R) Cross-Polarization (XP) Widefield Reflectance (WR)	Different; the WR filter has been introduced for the modified device as an alternative option to XP
OCTA scan types	Volume OCTA Scout OCTA DART Volume OCTA DART Line	Volume OCTA Scout OCTA DART Volume OCTA DART Line	Same
Lateral field of view (SLO)	SO (standard objective): 15°x15° to 30 x30° HMM: 8°x8° WFO2: 25°x25° to Ø 55° UWF Objective: 51°x 1° to Ø102°	SO (standard objective): 15°x15° to 30 x30° HMM: 8°x8° WFO2: 25°x25° to Ø 55° UWF Objective: 51°x 1° to Ø102°	Same
Lateral field of view (OCT)	Standard objective lens: 15°-30° WFO2: 25°-55°	Standard objective lens: 15°-30° WFO2: 25°-55°	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

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Lateral digital resolution (OCT)	Standard and WFO2 objective lenses: same as SLO	Standard and WFO2 objective lenses: same as SLO	Same
Digital axial resolution (pixel size OCT)	3.9 µm	3.9 µm	Same
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 high resolution mode: 768x768 to 1536 x 1536 pixels	Same
Acquisition of three-dimensional images	Yes, HRA: stacks of confocal section images; OCT: OCT volume scan	Yes HRA: stacks of confocal section images; OCT: OCT volume scan	Same
Glaucoma Module: BMO-MRW and RNFL thickness	Measured data points are displayed	Regression line is displayed for measured data points	Different, regression line has been added for measured data
Start of the acquisition module software	The acquisition module software is loaded by HEYEX as DLL file	New proxy DLL is loaded by Heyex and starts the acquisition module software as a new process	Different; the HEYEX and AQM software memory have been separated
Image compression	No	No	Same
Display of the data	Images are visible on a standard PC- Monitor	Images are visible on a standard PC- Monitor	Same
Physical layout	• Instrumentation mount with headrest • optical camera head • power supply and spectrometer unit • touch panel • computer with monitor, keyboard, mouse, and printer	• Instrumentation mount with headrest • optical camera head • power supply and spectrometer unit • touch panel • computer with monitor, keyboard, mouse, and printer	Same
Thunderbolt Interface	• Thunderbolt-2 Interface	• Thunderbolt-3 Interface with additional fan	Different; TDI-3 is applied because of discontinued TDI-2, additional cooling of Thunderbolt cable
Flammability of the materials	The metal housing of the device prevents flammability	The metal housing of the device prevents flammability	Same

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)	50mm working distance, 29mm length, 49mm outer diameter; not used for measurements;	50mm working distance, 29mm length, 49mm outer diameter; not used for measurements;	Same
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 (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
Supported Operating System	Windows 10	Windows 10 Windows 11	Different; Windows 11 is supported in addition to Windows 10

NON-CLINICAL PERFORMANCE TESTING

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

- ISO 14971: 2019 Medical Devices - Application of Risk Management to Medical Devices,
- AAMI / ANSI ES 60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 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.

Software documentation was provided, and software verification and validation was conducted as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Documentation regarding cybersecurity was submitted as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices".

CLINICAL PERFORMANCE TESTING

No data from human clinical studies has been included to support the substantial equivalence of the modified SPECTRALIS HRA+OCT and variants with the cleared SPECTRALIS device (K201252).

CONCLUSION

The modified SPECTRALIS HRA+OCT and variants measures the same ophthalmic features as the cleared SPECTRALIS HRA+OCT in K201252. The changes applied to the SPECTRALIS since the clearance in K201252 introduce an additional cSLO imaging suppression mode, a regression line for measured data in the Glaucoma Module, Thunderbolt-3 interface with cable fan and a separated start of the acquisition software module. They do not change the fundamental technology, the type of acquired images, the intended patient populations, or that 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 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 modified SPECTRALIS device is substantially equivalent to the predicate device.