July 1, 2024

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

Re: K240221
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: January 26, 2024
Received: May 31, 2024

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240221

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 January 25, 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

PREDICATE DEVICE

SPECTRALIS HRA+OCT and variants (K223557), 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)

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

- Addition of scan acquisitions for the SPECTRALIS OCT Angiography Module (OCTA) at 125 kH
- Addition of a General-Purpose Graphics Processing Unit (GPGPU)

COMPARISON BETWEEN THE SUBJECT AND THE PREDICATE DEVICE

The modified SPECTRALIS HRA+OCT and variants is a device modification to the cleared SPECTRALIS HRA+OCT and variants (K223557) predicate device. Detailed technological characteristics of the device are unchanged except for the modifications as stated above. 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

PREDICATE DEVICE K223557 SPECTRALIS HRA+OCT	SUBJECT DEVICE SPECTRALIS HRA+OCT	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 K223557 SPECTRALIS HRA+OCT	SUBJECT DEVICE SPECTRALIS HRA+OCT	Same or Different
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 angio-graphy: 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 angio-graphy: 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: 840 nm 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
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

	PREDICATE DEVICE K223557 SPECTRALIS HRA+OCT	SUBJECT DEVICE SPECTRALIS HRA+OCT	Same or Different
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 modes (A-scan rate)	40 kHz (Firewire) 85 kHz (Thunderbolt)	40 kHz (Firewire) 85 kHz (Thunderbolt) 125 kHz (Thunderbolt) for OCT Angiography only	Different; additional scan speed for OCTA
OCT real-time image processing	CPU	GPU (optional; with suitable graphics card only) CPU (else)	Different; porting of real-time processing to GPU (for all A-scan rates), when scan speed 125 kHz was activated
OCT acquisition modes	Standard Enhanced Depth Imaging (EDI) Enhanced Vitreous Imaging (EVI)	Standard Enhanced Depth Imaging (EDI) Enhanced Vitreous Imaging (EVI)	Same
OCTA scan types	Volume OCTA Scout Volume OCTA DART Line	Volume OCTA Scout Volume OCTA DART Line	Same
Lateral field of view (SLO)	SO (standard objective): 15°x15° to 30x30° HMM: 8°x8° WFO2: 25°x25° to Ø 55° UWF Objective: 51°x1° to Ø102°	SO (standard objective): 15°x15° to 30x30° HMM: 8°x8° WFO2: 25°x25° to Ø 55° UWF Objective: 51°x1° 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: 3 µm (HMM), 11 µm (SO) to 40 µm (UWF) High resolution mode: 1.5µm (HMM), 6 µm (SO) to 20 µm (UWF)	High speed mode: 3 µm (HMM), 11 µm (SO) to 40 µm (UWF) High resolution mode: 1.5µm (HMM), 6 µm (SO) to 20 µm (UWF)	Same
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 1536x1536 pixels	High speed mode: 384x384 pixels to 768x768 pixels high resolution mode: 768x768 to 1536x1536 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

	PREDICATE DEVICE K223557 SPECTRALIS HRA+OCT	SUBJECT DEVICE SPECTRALIS HRA+OCT	Same or Different
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
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)	50 mm working distance, 29 mm length, 49 mm outer diameter; not used for measurements;	50 mm working distance, 29 mm length, 49 mm 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, 49mm 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, 49mm 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 11	Windows 10 Windows 11	Same

NON-CLINICAL PERFORMANCE TESTING

Software documentation was provided, and software verification and validation were conducted as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions."

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

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" and an overall risk assessment regarding security and safety of the device was conducted due to ISO 14971:2019.

Tests for electrical safety (IEC 60601-1:2020) and electromagnetic compatibility (IEC 60601-1- 2:2020 and IEC TR 60601-4-2: 2016) were performed with the SPECTRALIS HRA+OCT device and passed the relevant requirements of the applied standards

Laser safety testing for the light sources used in the SPECTRALIS HRA+OCT device was provided and showed that the requirements according to FDA recognized standard ANSI Z80.36:2021 was fulfilled.

Biocompatibility of the device was demonstrated by cytotoxicity testing, skin sensitization testing and chemical analysis according to ISO 10993-5:2009, ISO 10993-10:2021 and ISO 10993-18:2005, respectively, and supported by biocompatibility assessment according to 10993-1:2018.

CLINICAL PERFORMANCE TESTING

One clinical, prospective, observational case study (S-2020-5) was performed at a single clinical site, located in the United States, to collect data in support of this 510(k) submission to add investigational OCTA scan types [HR10 @ 125 kHz, HS20 @ 125 kHz, Scout @ 125 kHz] to the SPECTRALIS with OCT Angiography Module (OCTA Module) device. The predicate device used in the study was the cleared SPECTRALIS HRA+OCT with OCTA Angiography Module scan types [HR10 @ 85 kHz, HS20 @ 85 kHz. There were two study populations, the "Normal population" (without ocular pathology) and the "Pathology population" (those with retinal vascular pathologies affecting different anatomic depths through the retina and choroid). Randomization was performed for the following: Eye selection (if applicable), dilated versus undilated OCTA imaging (Normal population only), and scan type order (which includes device order).

Three independent reviewers from a reading center graded the OCTA scans on image quality, visibility of key anatomical vascular structures, and identification of pathologies. The analyses were based on the grading results from the effectiveness analysis population, which included all eligible study eyes with an OCTA image result for at least one investigational scan type (125 kHz) from the reading center.

Data were collected for agreement analysis to show substantial equivalence between

the investigational study device and stated predicate. Eighty-six (86) subjects signed the informed consent form and were enrolled in the study. Of the 86 subjects enrolled, 80 completed the study and six subjects were discontinued. Four subjects (one Normal, three Pathology) were discontinued due to failure to meet inclusion/exclusion criteria, one Pathology subject was discontinued due to "Region of Interest not within view" and one subject was discontinued due to an adverse event[1] [subject reported eye pain due to panretinal photocoagulation (PRP) in the fellow eye, which occurred just prior to study imaging]. One Normal subject completed the study but was identified as "Failure to meet inclusion/exclusion criteria" during study monitoring.

The safety population consisted of 84 subjects, 27 Normal subjects and 57 Pathology subjects. The effectiveness analysis population consisted of 79 subjects, 25 Normal subjects and 54 Pathology subjects. However, this effectiveness count ranges for direct comparison between the predicate device and the investigational device depending on the scan type.

All 79 participants in the effectiveness analysis population were 22 years of age or older, met eligibility criteria in at least one eye and were enrolled into either the "Normal population" or the "Pathology population".

The study included 65.8% female and 34.2% male participants. The mean age was 58.6 ± 13.8 years overall, with the Pathology population subjects being older. Ninety-four percent (94%) were not Hispanic or Latino, and 67% were Caucasian. Thirty percent (30%) were Black/African American and two percent (2%) were Asian.

Based on the eye examination, the eyes in the Normal population did not have any retinal conditions or abnormalities reported. The eyes in the Pathology population had the highest frequency of the following retinal conditions: wet age-related macular degeneration (nARMD) (16.7%), non-proliferative diabetic retinopathy (NPDR) (16.7%), proliferative diabetic retinopathy (PDR) (37.0%), and macular telangiectasia (Mac Tel) (14.8%). The highest reported abnormalities in the Pathology population were microaneurysm (MA) (46.3%), choroidal neovascularization (CNV) (24.1%), and retinal neovascularization (RNV) (20.4%).

The results of this study found that based on the proportion of images graded better than Poor on consensus in the effectiveness population, 96.2% of HR10 @ 125 kHz, 98.7% of HS20 @ 125 kHz, and 98.7% of Scout @ 125 kHz images from the investigational SPECTRALIS scan types were assessed as having overall image quality sufficient to assess the clinically relevant content. Additionally, based on the proportion of structures graded better than Unable to Distinguish, visualization of key anatomic structures on the investigational SPECTRALIS scan types was achieved on at least 92.3% of assessments performed on the HR10 @ 125 kHz scan type, ≥ 93.6% on HS20 @ 125 kHz, and ≥ 96.2% on Scout @ 125 kHz. In general, the results demonstrate that the investigational SPECTRALIS OCTA images provide similar visibility as compared to the predicate (85 kHz).

For the agreement in identification of vascular abnormalities [microaneurysms (MA), retinal ischemia (RI), retinal neovascularization (RNV), choroidal neovascularization

[1] There was only one adverse event that occurred during the course of the study.

(CNV)] between the predicate scan types and the corresponding investigational scan types, agreement was assessed by the vascular abnormalities identified from the predicate scan types. Agreement rate, PPA and NPA were greater than or equal to 88.7% for all pre-specified vascular abnormalities (except for RI, which was 86.5% in the Pathology population) for both scan patterns (10x10 HR and 20x20 HS), in all subject populations. Similarly, for identification of the primary vascular abnormality of interest (PVAOI), the agreement rate, PPA and NPA was at least 85.7% for the 10x10 HR scan types and at least 92.3% for 20x20 HS scan types, in all subject populations. The results are similar between the investigational scan types and the predicate scan types, indicating that the ability to identify each pre-specified vascular abnormality is similar between the predicate and investigational scan types.

CONCLUSION

The modified SPECTRALIS HRA+OCT and variants measures the same ophthalmic features as the cleared SPECTRALIS HRA+OCT in K223557. The additional scan speed and the correlated GPGPU processing 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. Results of the non-clinical performance testing demonstrate that the subject SPECTRALIS device functions as intended. The clinical study shows similar results for the predicate and investigational scan types for the SPECTRALIS with OCTA Module with regard to image quality, the ability to visualize key vascular anatomical structures, and the ability to identify various vascular abnormities. The non-clinical and clinical performance testing demonstrate that the subject SPECTRALIS device is as safe, as effective, and thus substantially equivalent to the predicate device.