May 7, 2026

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

Re: K253837
Trade/Device Name: SPECTRALIS HRA+OCT and variants; SPECTRALIS with Flex Module
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO, MYC
Dated: December 1, 2025
Received: December 1, 2025

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Alexander Beylin -S Date: 2026.05.07 11:38:09 -04'00'

for CAPT Bradley Cunningham, MSE, RAC
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253837	?

Please provide the device trade name(s). ?

(1) SPECTRALIS HRA+OCT and variants;
(2) SPECTRALIS with Flex Module

Please provide your Indications for Use below. ?

(1) SPECTRALIS HRA+OCT and variants:
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
• 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)

(2) SPECTRALIS with Flex Module:
The SPECTRALIS with Flex Module is a non-contact ophthalmic diagnostic imaging device intended to aid in the visualization of the posterior segment structures of the eye and vasculature of the retina and choroid. SPECTRALIS with Flex Module is intended for imaging of adults and pediatric patients in supine position.

Please select the types of uses (select one or both, as applicable). ?

☒ Prescription Use (21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY

Date Prepared May 05, 2026

SPONSOR/510(K) OWNER/ MANUFACTURER

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Establishment Registration No.: 8043762

OFFICIAL CONTACT PERSON

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Orasi Consulting, LLC.
226 1st Street
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E-mail: lena@orasiconsulting.com

COMMON/USUAL NAME

Optical Coherence Tomography

PROPRIETARY OR TRADE NAMES

SPECTRALIS HRA+OCT and variants;

SPECTRALIS with Flex Module

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 DEVICES

SPECTRALIS HRA+OCT and variants (K250868), Heidelberg Engineering GmbH;

SPECTRALIS with Flex Module (K241163), Heidelberg Engineering GmbH

REFERENCE DEVICE

CIRRUS HD-OCT 5000 (K150977), Carl Zeiss Meditec Inc.

INDICATIONS FOR USE

SPECTRALIS HRA+OCT and variants

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
- 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)

SPECTRALIS with Flex Module

The SPECTRALIS with Flex Module is a non-contact ophthalmic diagnostic imaging device intended to aid in the visualization of the posterior segment structures of the eye and vasculature of the retina and choroid. SPECTRALIS with Flex Module is intended for imaging of adults and pediatric patients in supine position.

GENERAL DEVICE DESCRIPTION

This 510(k) submission bundles the following SPECTRALIS devices:

1) SPECTRALIS HRA+OCT and variants (lastly cleared in K250868) and

2) SPECTRALIS with Flex Module (cleared in K241163).

The SPECTRALIS is an OCT ophthalmic imaging device with two configurations: a tabletop configuration, where the SPECTRALIS is placed on a fixed instrumentation mount (SPECTRALIS HRA+OCT and variants, K250868) and a mobile configuration, where the SPECTRALIS is placed on a mobile instrumentation mount to enable imaging in the supine position (SPECTRALIS with Flex Module, K241163). Both “SPECTRALIS HRA+OCT and variants” and “SPECTRALIS with Flex Module” share the same HRA and OCT technologies and use the same SPECTRALIS software.

The SPECTRALIS HRA+OCT device 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.

This submission includes device modifications which are either applicable to both SPECTRALIS HRA+OCT and variants and SPECTRALIS with Flex Module, or only to one of the two device configurations. The subject software version, applicable for both SPECTRALIS HRA+OCT and variants and SPECTRALIS with Flex Module is Version 7.4.

#	Modification	SPECTRALIS HRA+OCT and variants	SPECTRALIS with Flex Module
1	Green Autofluorescence Imaging	x	x
2	Internal data-handling changes for eye tracking during OCTA acquisitions	x	x
3	Blue Laser: Optional reduction of laser power	x	x
4	Discontinuation of the earlier data management system HEYEX	x	x
5	Glaucoma Module Premium Edition (GMPE) software extension: Change Analysis tab with Macula Grid for PPoleH Scans	x	-
6	Mechanical adjustments of the Flex Module mount (Hardware)	-	x

COMPARISON BETWEEN THE SUBJECT AND THE PREDICATE DEVICE

SUBJECT DEVICE: SPECTRALIS HRA+OCT and variants

The modified tabletop SPECTRALIS HRA+OCT and variants is a device modification to the cleared SPECTRALIS HRA+OCT and variants (K250868) predicate device. Technological characteristics of the device are unchanged except for the modifications as stated above. The modified HRA+OCT and variants has the same intended use and maintains the same fundamental scientific technology as the predicate device. The Indications for Use Statement has been updated to reflect the additional green autofluorescence imaging (GAF) provided for all SPECTRALIS HRA+OCT variants under the existing indication for autofluorescence imaging.

The Substantial Equivalence summary tables below illustrate the comparisons of the modified SPECTRALIS HRA+OCT and variants to the predicate device.

HEIDELBERG ENGINEERING

INDICATIONS FOR USE STATEMENT CHART

(Differences are highlighted in grey)

SUBJECT DEVICE SPECTRALIS HRA+OCT and variants	PREDICATE DEVICE K250868 SPECTRALIS HRA+OCT and variants	
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 • 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)	Similar: Clarification due to the addition of Green Autofluorescence imaging (GAF) available for all variants

HEIDELBERG ENGINEERING

TECHNOLOGICAL CHARACTERISTICS COMPARISON CHART

(Differences are highlighted in grey)

	SUBJECT DEVICE SPECTRALIS HRA+OCT and variants	PREDICATE DEVICE K250868 SPECTRALIS HRA+OCT and variants	Same, Similar 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: 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

	SUBJECT DEVICE SPECTRALIS HRA+OCT and variants	PREDICATE DEVICE K250868 SPECTRALIS HRA+OCT and variants	Same, Similar or Different
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
cSLO Imaging Modes	• Infrared reflectance imaging (IR) • Blue reflectance imaging (BR) • MultiColor (IR, blue, green) • Fluorescein angiography (FA) • Indocyanine green angiography (ICGA) • Infrared Autofluorescence imaging (IRAF) • "BluePeak" Autofluorescence fundus imaging (BAF) • Simultaneous FA+ICGA • Simultaneous FA+IR • Simultaneous ICGA+IR • Green autofluorescence imaging (GAF) • Simultaneous BAF+GAF	• Infrared reflectance imaging (IR) • Blue reflectance imaging (BR) • MultiColor (IR, blue, green) • Fluorescein angiography (FA) • Indocyanine green angiography (ICGA) • Infrared Autofluorescence imaging (IRAF) • "BluePeak" Autofluorescence fundus imaging (BAF) • Simultaneous FA+ICGA • Simultaneous FA+IR • Simultaneous ICGA+IR	Different: - New imaging mode added (GAF) - Uses existing 518 nm laser from MultiColor for Autofluorescence excitation. - Same detection principle as BAF
Optional reduced laser power	• IR • BR • MultiColor • FA • ICGA • IRAF • BAF	• IR • BR • MultiColor • FA • ICGA • IRAF	Similar: Option for different laser powers now available for further (existing) imaging mode (BAF)
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 modes (A-scan rate)	40 kHz (Firewire) 85 kHz (Thunderbolt) 125 kHz (Thunderbolt), for OCT Angiography only 250 kHz (Thunderbolt), for OCT Angiography only	40 kHz (Firewire) 85 kHz (Thunderbolt) 125 kHz (Thunderbolt), for OCT Angiography only 250 kHz (Thunderbolt), for OCT Angiography only	Same
OCT EYE Tracking	TruTrack Active Eye Tracking	TruTrack Active Eye Tracking	
OCTA Eye Tracking	TruTrack Active Eye Tracking	TruTrack Active Eye Tracking	Similar: Same feature, different software processing of the

	SUBJECT DEVICE SPECTRALIS HRA+OCT and variants	PREDICATE DEVICE K250868 SPECTRALIS HRA+OCT and variants	Same, Similar or Different
			eye tracking for OCTA
OCT real-time image processing	GPU (optional; with suitable graphics card only) CPU (else)	GPU (optional; with suitable graphics card only) CPU (else)	Same
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	Standard: Volume OCTA Scout: Volume OCTA DART: Volume OCTA, Line OCTA	Standard: Volume OCTA Scout: Volume OCTA DART: Volume OCTA, Line OCTA	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
Glaucoma Module Premium Edition (GMPE) – PPoleH scan pattern	• ETDRS Grid with retinal thickness parameters: - Macular Total Retinal Thickness (TRT) - Macular Nerve Fiber Layer Thickness (NFL) - Macular Ganglion Cell Layer Thickness (GCL) - Macular Inner Plexiform Layer Thickness (IPL) • Change Analysis tab displaying existing parameters (TRT, NFL, GCL, IPL) and two combined	• ETDRS Grid with retinal thickness parameters: - Macular Total Retinal Thickness (TRT) - Macular Nerve Fiber Layer Thickness (NFL) - Macular Ganglion Cell Layer Thickness (GCL) - Macular Inner Plexiform Layer Thickness (IPL)	Different: - Addition of change analysis tab - Addition of macula grids

	SUBJECT DEVICE SPECTRALIS HRA+OCT and variants	PREDICATE DEVICE K250868 SPECTRALIS HRA+OCT and variants	Same, Similar or Different
	parameters: - GCL+IPL - Macular Ganglion Cell Complex Thickness (GCC) • Macula Grid		
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 and optional • 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	10 mm working distance, 46 mm length, 49mm outer diameter; 55° field of view; not used for measurements	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
Patient Data Management System	• External PACS/ MIMPS	• External PACS/ MIMPS • HEYEX	Similar: HEYEX was the earlier data management system now phased out and replaced by HEYEX 2 / HEYEX PACS. Compatibility with external systems (MIMPS) is maintained.

SUBJECT DEVICE: SPECTRALIS with Flex Module

The modified tabletop SPECTRALIS with Flex Module is a device modification to the cleared SPECTRALIS with Flex Module (K241163) predicate device. Technological characteristics of the device are unchanged except for the modifications as stated above. The modified SPECTRALIS with Flex Module has the same intended use, Indications for Use and maintains the same fundamental scientific technology as the device.

The Substantial Equivalence summary tables below illustrate the comparisons of the modified SPECTRALIS with Flex Module to the predicate device.

INDICATIONS FOR USE STATEMENT CHART

(Differences are highlighted in grey)

SUBJECT DEVICE SPECTRALIS with Flex Module	PREDICATE DEVICE K241163 SPECTRALIS with Flex Module	Same, Similar or Different
The SPECTRALIS with Flex Module is a non-contact ophthalmic diagnostic imaging device intended to aid in the visualization of the posterior segment structures of the eye and vasculature of the retina and choroid. SPECTRALIS with Flex Module is intended for imaging of adults and pediatric patients in supine position.	The SPECTRALIS with Flex Module is a non-contact ophthalmic diagnostic imaging device intended to aid in the visualization of the posterior segment structures of the eye and vasculature of the retina and choroid. SPECTRALIS with Flex Module is intended for imaging of adults and pediatric patients in supine position.	Same

TECHNOLOGICAL CHARACTERISTICS COMPARISON CHART

(Differences are highlighted in grey)

	SUBJECT DEVICE SPECTRALIS with Flex Module	PREDICATE DEVICE K241163 SPECTRALIS with Flex Module	Same, Similar 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 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

	SUBJECT DEVICE SPECTRALIS with Flex Module	PREDICATE DEVICE K241163 SPECTRALIS with Flex Module	Same, Similar or Different
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: 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
cSLO Imaging Modes	• Infrared reflectance imaging (IR) • Blue reflectance imaging (BR) • MultiColor (IR, blue, green) • Fluorescein angiography (FA) • Indocyanine green angiography (ICGA) • Infrared Autofluorescence imaging (IRAF) • “BluePeak” Autofluorescence fundus imaging (BAF) • Simultaneous FA+ICGA • Simultaneous FA+IR • Simultaneous ICGA+IR • Green autofluorescence imaging (GAF) • Simultaneous BAF+GAF	• Infrared reflectance imaging (IR) • Blue reflectance imaging (BR) • MultiColor (IR, blue, green) • Fluorescein angiography (FA) • Indocyanine green angiography (ICGA) • Infrared Autofluorescence imaging (IRAF) • “BluePeak” Autofluorescence fundus imaging (BAF) • Simultaneous FA+ICGA • Simultaneous FA+IR • Simultaneous ICGA+IR	Different: - New imaging mode added (GAF) - Uses existing 518 nm laser from MultiColor for Autofluorescence excitation. - Same detection principle as BAF

	SUBJECT DEVICE SPECTRALIS with Flex Module	PREDICATE DEVICE K241163 SPECTRALIS with Flex Module	Same, Similar or Different
Optional reduced laser power	• IR • BR • MultiColor • FA • ICGA • IRAF • BAF	• IR • BR • MultiColor • FA • ICGA • IRAF	Similar: Option for different laser powers now available for further (existing) imaging mode (BAF)
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 modes (A-scan rate)	85 kHz (Thunderbolt)	85 kHz (Thunderbolt)	Same
OCT Eye Tracking	TruTrack Active Eye Tracking	TruTrack Active Eye Tracking	Similar: Same feature, different software processing of the eye tracking for OCTA
OCT real-time image processing	GPU (optional; with suitable graphics card only) CPU (else)	GPU (optional; with suitable graphics card only) CPU (else)	Same
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	Standard: Volume OCTA Scout: Volume OCTA DART: Volume OCTA, Line OCTA	Standard: Volume OCTA Scout: Volume OCTA DART: Volume OCTA, Line OCTA	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

	SUBJECT DEVICE SPECTRALIS with Flex Module	PREDICATE DEVICE K241163 SPECTRALIS with Flex Module	Same, Similar or Different
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
Measurements	Measured data points are not displayed	Measured data points are not displayed	Same
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	• Mobile instrumentation mount with swivel arms for camera and accessories • Optical camera head • Power supply and spectrometer unit • Touch panel • Computer with monitor, keyboard, mouse, and printer	• Mobile instrumentation mount with swivel arms for camera and accessories • Optical camera head • Power supply and spectrometer unit • Touch panel • Computer with monitor, keyboard, mouse, and printer	Similar: Types of components are the same, only mechanical adjustments of the instrumentation mount
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 not used for measurements	19.5 mm working distance, 31 mm length, 49 outer mm diameter not used for measurements	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
Wide Field Objective (WFO2)	10 mm working distance, 46 mm length, 49mm outer diameter; 55° field of view; not used for measurements	10 mm working distance, 46 mm length, 49mm outer diameter; 55° field of view; not used for measurements	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 workingdistance, 167 mm length, 80 mm outer diameter; 102° field of view; not used for measurements	Same
Patient Data Management System	External PACS/ MIMPS	• External PACS/ MIMPS • HEYEX	Similar: HEYEX represented the previous alternative patient data management system. The compatibility to the existing external MIMPS (HEYEX 2/ HEYEX PACS) is maintained.

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" 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 SPECTRALIS with Flex Module and/ or with SPECTRALIS HRA+OCT and variants and passed the relevant requirements of the applied standards.

Laser safety testing for the light sources used in the SPECTRALIS HRA+OCT and variants and in SPECTRALIS with Flex Module was previously provided and showed that the requirements according to FDA recognized standard ANSI Z80.36:2021 were fulfilled. The test results remain valid for the subject devices.

Biocompatibility of the tabletop SPECTRALIS HRA+OCT and variants was previously 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. The test results remain valid for the subject tabletop SPECTRALIS HRA+OCT and variants.

CLINICAL PERFORMANCE TESTING

(Applicable for the subject SPECTRALIS HRA+OCT and variants only)

One prospective, randomized precision and agreement study (S-2018-2) was conducted at one clinical site in the United States to assess the agreement of the macular parameters of the (tabletop) Heidelberg Engineering SPECTRALIS HRA+OCT with Glaucoma Module Premium Edition compared to those derived from the Zeiss Cirrus HD-OCT 5000, or for parameters not provided by the Cirrus, to manual segmentation of the SPECTRALIS acquisitions by an independent reading center. In addition, the repeatability and reproducibility of the macular parameters were assessed for both the SPECTRALIS HRA+OCT and the Cirrus and compared for parameters available on both devices.

There were three study populations—Normal eyes population (without ocular pathology), eyes with Retinal Disease population, and eyes with Glaucoma population. Participants aged 22 years or older who met eligibility criteria in at least one eye were assigned to an eye population, randomized and underwent study imaging on each of three SPECTRALIS and three Cirrus devices by three operators, where each operator was paired with one SPECTRALIS device and one Cirrus device to form three

configurations. For all eye populations, the scan patterns acquired on the study eye from each device for analysis were the SPECTRALIS PPoleH, and the Cirrus Macular Cube 200 x 200. Imaging was attempted until a minimum of three acceptable study scans had been acquired for each device, per configuration, or until a maximum of nine (9) attempts had been reached. The follow-up registration feature was not used for either study device.

In cases where the automated segmentation boundaries needed to be corrected, this was done by the clinical site with the segmentation tools as per each device's user manual.

To validate the SPECTRALIS macular parameters not provided by the Cirrus, three independent graders from the Boston Image Reading Center (BIRC) manually segmented the NFL, GCL, and IPL boundaries on the first acceptable SPECTRALIS PPoleH scan for the Normal and Glaucoma populations.

Of the 86 participants enrolled, 74 participants met all eligibility criteria in at least one eye and were randomized and scanned. The precision analysis population consisted of 73 participants: 25 Normal eyes, 24 eyes with Retinal Disease and 24 eyes with Glaucoma. The agreement analysis population consisted of 72 participants: 24 Normal eyes, 24 eyes with Retinal Disease and 24 eyes with Glaucoma.

The study included 60.8% male and 39.2% female participants. The mean age was 57.3 ± 16.6 years overall, with the Retinal Disease and Glaucoma eye population participants being older. A majority (66.2%) were not Hispanic or Latino, 44.6% were Black/African American and 41.9% were Caucasian; all other race distributions were less than ten percent.

Rates of scan acquisition acceptability, as determined by the site, were better for SPECTRALIS than Cirrus for all three eye populations (Normal, 95.6% vs 92.9%; Retinal Disease, 89.8% vs 68.1%; Glaucoma, 92.9% vs. 84.6%).

Agreement

For Normal eyes and Glaucoma eyes, the GCL+IPL thickness via Macular Grid was thicker on the SPECTRALIS than the Cirrus, which is a systematic difference attributable to the SPECTRALIS having a smaller grid. The thicker measurements from SPECTRALIS' Macular Grid can arise from averaging values from the thicker tissue surrounding the fovea, while the larger Cirrus grid encompasses the same area but also includes retinal tissue more peripherally, which is typically thinner, leading to lower average thicknesses. In the current study, the mean difference between SPECTRALIS and Cirrus in Normal eyes ranged from 6.3 to 10.5μm (mean GCL+IPL thickness SPECTRALIS 90.1 vs Cirrus 81.4μm for Global value) and the mean difference in eyes with Glaucoma ranged from 1.3 to 8.6μm (mean GCL+IPL thickness SPECTRALIS 70.1 vs Cirrus 64.8μm for Global value).

The mean measurements of TRT via ETDRS Grid from SPECTRALIS were thicker than those from the Cirrus for all three eye populations (Normal, Retinal Disease, and Glaucoma), as expected, primarily due to the different definitions of TRT between devices (SPECTRALIS measures TRT as [ILM-BM] and Cirrus measures [ILM-RPE]).

The mean difference between SPECTRALIS and Cirrus in Normal eyes ranged from 16.3 to 22.2µm, in eyes with Retinal Disease ranged from 13.0 to 17.7µm , and in eyes with Glaucoma ranged from 15.0 to 17.4µm. The mean ETDRS Grid TRT (1mm Central sector) measurements obtained in the study for SPECTRALIS and Cirrus, respectively, were 267.5 vs 251.1µm in Normal eyes, 271.7 vs 257.2µm in eyes with Retinal Disease, and 249.7 vs 234.7µm in eyes with Glaucoma. These mean differences found were fairly consistent between eye populations and comparable to the differences expected based on the available literature.

Presented in Figure 1 below is a summary of the limits of agreement results and the corresponding 95% CIs of the lower LoA and upper LoA for the parameters compared between SPECTRALIS and Cirrus. Note that the difference is calculated as SPECTRALIS – Cirrus, where positive differences indicate that SPECTRALIS measures thicker. Due to such device-specific differences, retinal thickness measurements should not be considered interchangeable.

In comparisons of the SPECTRALIS measurements to the average measurement via manual segmentation by three independent graders, Macular Grid NFL, GCL, IPL and GCC (i.e., NFL+GCL+IPL) thickness each measured either slightly thinner or thicker on SPECTRALIS by ≤ 4.2µm (as determined by mean difference, where NFL was thinner, GCL was thinner, IPL was thicker in Normal, IPL was thinner in Glaucoma, and GCC was thinner). Agreement results are summarized in Figures 2 and 3 below. These results are reasonable considering the SPECTRALIS' axial resolution of 7µm optically and 3.9µm digitally.

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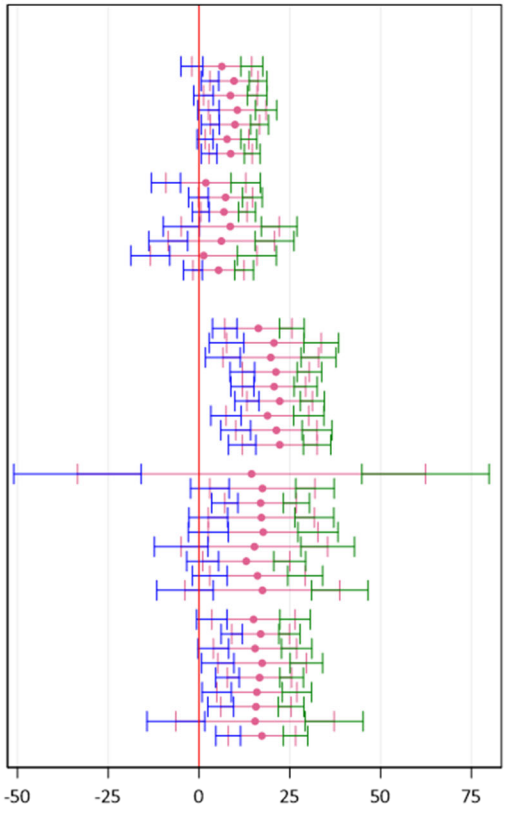
Figure 1 LOA Summary of Macula Grid GCL + IPL and ETDRS Grid TRT Parameters between SPECTRALIS and Cirrus Measurements, Agreement Analysis Population

Parameter (µm)	N	Limit of Agreement (LoA)	95% CI of Lower Limit of LoA	95% CI of Upper Limit of LoA	SPECTRALIS Range	Cirrus Range	Estimated Clinical Range
GCL+IPL							
Normal							
Superior Temporal	24	(-2.0, 14.5)	(-5.0, 1.0)	(11.5, 17.5)	(65, 102)	(62, 92)	(60.1, 100.8)
Superior	24	(3.0, 16.3)	(0.6, 5.4)	(13.8, 18.7)	(70, 106)	(62, 92)	(56.5, 102.5)
Superior Nasal	24	(1.2, 16.0)	(-1.5, 3.9)	(13.3, 18.7)	(69, 107)	(65, 97)	(61.2, 106.0)
Inferior Nasal	24	(2.6, 18.5)	(-0.3, 5.5)	(15.6, 21.4)	(69, 106)	(63, 96)	(59.1, 103.8)
Inferior	24	(3.1, 16.7)	(0.6, 5.6)	(14.2, 19.1)	(69, 104)	(62, 91)	(53.6, 101.1)
Inferior Temporal	24	(1.7, 13.7)	(-0.5, 3.9)	(11.5, 15.9)	(69, 105)	(63, 94)	(59.0, 101.6)
Global Value	24	(2.8, 14.6)	(0.6, 4.9)	(12.5, 16.8)	(68, 104)	(63, 94)	(56.1, 102.6)
Glaucoma							
Superior Temporal	24	(-9.1, 12.9)	(-13.1, -5.1)	(8.8, 16.9)	(43, 91)	(45, 82)	(37.6, 93.4)
Superior	24	(-0.2, 14.7)	(-2.9, 2.6)	(12.0, 17.4)	(46, 92)	(42, 80)	(38.4, 98.4)
Superior Nasal	24	(0.5, 13.2)	(-1.8, 2.8)	(10.9, 15.6)	(54, 97)	(49, 86)	(42.1, 99.1)
Inferior Nasal	24	(-4.9, 22.1)	(-9.8, 0.0)	(17.1, 27.0)	(41, 96)	(47, 83)	(36.9, 96.1)
Inferior	24	(-8.5, 20.8)	(-13.9, -3.1)	(15.4, 26.1)	(36, 93)	(48, 83)	(35.4, 93.4)
Inferior Temporal	24	(-13.4, 15.9)	(-18.8, -8.0)	(10.6, 21.3)	(39, 97)	(44, 90)	(33.0, 96.3)
Global Value	24	(-1.7, 12.4)	(-4.3, 0.9)	(9.8, 15.0)	(49, 92)	(47, 82)	(39.7, 103.5)
TRT							
Normal							
1mm Central	24	(7.1, 25.6)	(3.7, 10.5)	(22.2, 29.0)	(226, 331)	(212, 311)	(202.3, 327.5)
3mm Superior	24	(7.6, 33.7)	(2.8, 12.4)	(28.9, 38.4)	(286, 369)	(263, 347)	(274.9, 377.3)
3mm Nasal	24	(6.6, 32.9)	(1.8, 11.4)	(28.1, 37.7)	(287, 366)	(266, 346)	(273.8, 379.2)
3mm Inferior	24	(11.9, 30.4)	(8.6, 15.3)	(27.0, 33.8)	(285, 364)	(262, 338)	(274.6, 382.6)
3mm Temporal	24	(12.0, 29.4)	(8.8, 15.1)	(26.2, 32.5)	(274, 356)	(254, 330)	(268.7, 364.9)
6mm Superior	24	(13.2, 31.2)	(9.9, 16.5)	(27.9, 34.5)	(259, 326)	(233, 302)	(236.5, 325.8)
6mm Nasal	24	(7.4, 30.2)	(3.3, 11.6)	(26.1, 34.4)	(268, 338)	(241, 323)	(252.5, 358.8)
6mm Inferior	24	(10.1, 32.5)	(6.0, 14.2)	(28.4, 36.6)	(248, 310)	(224, 289)	(228.6, 328.4)
6mm Temporal	24	(11.9, 32.5)	(8.1, 15.7)	(28.8, 36.3)	(239, 305)	(219, 279)	(224.6, 315.0)
Retinal Disease							
1mm Central	24	(-33.5, 62.4)	(-51.0, -15.9)	(44.9, 79.9)	(112, 420)	(166, 398)	(50.1, 965.0)
3mm Superior	24	(3.0, 31.9)	(-2.3, 8.3)	(26.6, 37.2)	(226, 438)	(219, 400)	(240.0, 893.0)
3mm Nasal	24	(7.1, 26.8)	(3.5, 10.7)	(23.2, 30.4)	(238, 465)	(210, 453)	(210.0, 887.0)
3mm Inferior	24	(2.6, 31.8)	(-2.8, 7.9)	(26.4, 37.1)	(230, 456)	(220, 442)	(210.0, 897.0)
3mm Temporal	24	(2.9, 32.8)	(-3.0, 8.1)	(27.2, 38.3)	(208, 467)	(198, 430)	(204.0, 948.0)
6mm Superior	24	(-4.9, 35.4)	(-12.3, 2.5)	(28.0, 42.8)	(217, 343)	(240, 317)	(245.0, 421.0)
6mm Nasal	24	(1.0, 25.0)	(-3.4, 5.4)	(20.6, 29.4)	(221, 348)	(226, 333)	(274.0, 376.0)
6mm Inferior	24	(2.9, 29.2)	(-1.9, 7.8)	(24.4, 34.0)	(211, 354)	(202, 331)	(243.0, 399.0)
6mm Temporal	24	(-3.9, 38.8)	(-11.6, 3.9)	(31.0, 46.6)	(206, 377)	(207, 364)	(175.0, 474.0)
Glaucoma							
1mm Central	24	(3.5, 26.5)	(-0.6, 7.7)	(22.3, 30.6)	(216, 302)	(199, 287)	(203.2, 320.1)
3mm Superior	24	(9.0, 24.9)	(6.1, 11.9)	(22.0, 27.8)	(272, 343)	(256, 328)	(259.0, 368.1)
3mm Nasal	24	(4.0, 26.9)	(-0.2, 8.1)	(22.7, 31.1)	(288, 350)	(270, 335)	(268.0, 369.4)
3mm Inferior	24	(5.2, 29.6)	(0.7, 9.6)	(25.1, 34.0)	(274, 345)	(253, 331)	(255.4, 361.9)
3mm Temporal	24	(7.8, 25.5)	(4.6, 11.1)	(22.3, 28.7)	(266, 339)	(249, 326)	(251.8, 349.5)
6mm Superior	24	(4.9, 26.9)	(0.9, 8.9)	(22.9, 31.0)	(240, 285)	(224, 273)	(226.2, 322.4)
6mm Nasal	24	(6.0, 25.4)	(2.4, 9.5)	(21.8, 28.9)	(253, 313)	(231, 301)	(238.1, 340.3)
6mm Inferior	24	(-6.4, 37.2)	(-14.3, 1.6)	(29.2, 45.2)	(232, 288)	(212, 287)	(212.1, 301.1)
6mm Temporal	24	(8.0, 26.6)	(4.6, 11.4)	(23.2, 30.0)	(231, 282)	(216, 268)	(216.5, 327.1)



Difference = SPECTRALIS – Cirrus

GCL+IPL: Macular Grid Ganglion Cell Layer + Inner Plexiform Layer

TRT: ETDRS Grid Total Retinal Thickness

Estimated Clinical Range was derived per literature search.

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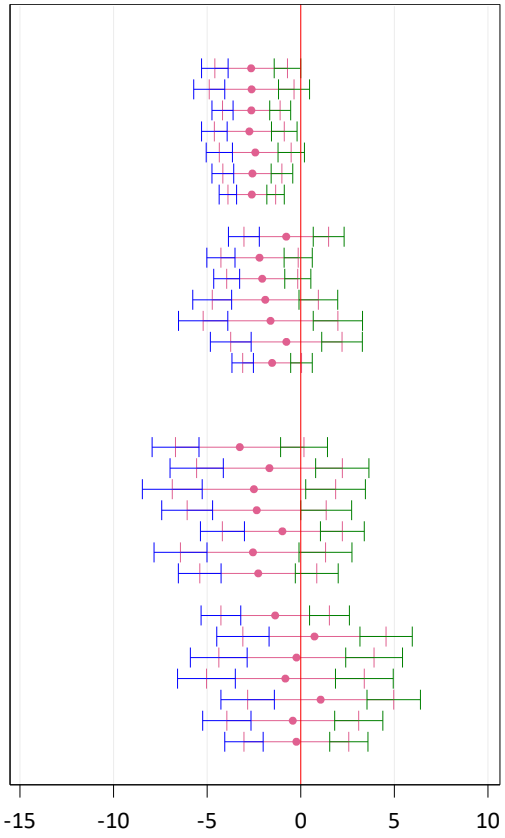
Figure 2 LOA Summary of Macular Grid NFL and GCL Parameters between SPECTRALIS and Manual Measurements, Agreement Analysis Population

Parameter (µm)	N	Limit of Agreement (LoA)	95% CI of Lower Limit of LoA	95% CI of Upper Limit of LoA	SPECTRALIS Range	Average Manual Range	Estimated Clinical Range
NFL							
Normal							
Superior Temporal	24	(-4.6, -0.7)	(-5.3, -3.9)	(-1.4, 0.0)	(15, 19)	(18, 22)	**
Superior	24	(-4.9, -0.4)	(-5.7, -4.1)	(-1.2, 0.5)	(18, 30)	(22, 31)	(19.5, 35.2)
Superior Nasal	24	(-4.2, -1.1)	(-4.7, -3.6)	(-1.7, -0.5)	(19, 30)	(23, 33)	**
Inferior Nasal	24	(-4.6, -0.9)	(-5.3, -3.9)	(-1.6, -0.2)	(20, 29)	(22, 31)	**
Inferior	24	(-4.3, -0.5)	(-5.0, -3.6)	(-1.2, 0.2)	(21, 32)	(23, 35)	(19.3, 34.1)
Inferior Temporal	24	(-4.2, -1.0)	(-4.7, -3.6)	(-1.6, -0.4)	(17, 22)	(20, 25)	**
Global Value	24	(-3.9, -1.3)	(-4.4, -3.4)	(-1.8, -0.9)	(20, 26)	(23, 28)	**
Glaucoma							
Superior Temporal	24	(-3.0, 1.5)	(-3.9, -2.2)	(0.7, 2.3)	(15, 23)	(15, 25)	**
Superior	24	(-4.3, -0.1)	(-5.0, -3.5)	(-0.9, 0.6)	(13, 38)	(16, 40)	(16.3, 29.9)
Superior Nasal	24	(-4.0, -0.2)	(-4.7, -3.3)	(-0.9, 0.5)	(17, 31)	(19, 34)	**
Inferior Nasal	24	(-4.7, 0.9)	(-5.8, -3.7)	(-0.1, 2.0)	(16, 34)	(15, 35)	**
Inferior	24	(-5.2, 2.0)	(-6.5, -3.9)	(0.7, 3.3)	(16, 30)	(14, 33)	(14.4, 30.0)
Inferior Temporal	24	(-3.7, 2.2)	(-4.8, -2.7)	(1.1, 3.3)	(15, 24)	(15, 26)	**
Global Value	24	(-3.1, 0.0)	(-3.7, -2.5)	(-0.5, 0.6)	(16, 27)	(18, 28)	**
GCL							
Normal							
Superior Temporal	24	(-6.7, 0.2)	(-7.9, -5.4)	(-1.1, 1.4)	(34, 57)	(33, 61)	**
Superior	24	(-5.6, 2.2)	(-7.0, -4.1)	(0.8, 3.6)	(39, 60)	(37, 62)	(40.6, 63.4)
Superior Nasal	24	(-6.9, 1.9)	(-8.5, -5.3)	(0.3, 3.5)	(38, 62)	(35, 65)	**
Inferior Nasal	24	(-6.1, 1.4)	(-7.4, -4.7)	(0.0, 2.7)	(38, 59)	(35, 64)	**
Inferior	24	(-4.2, 2.2)	(-5.4, -3.0)	(1.1, 3.4)	(38, 59)	(37, 60)	(41.5, 63.0)
Inferior Temporal	24	(-6.4, 1.3)	(-7.8, -5.0)	(-0.1, 2.7)	(39, 58)	(37, 61)	**
Global Value	24	(-5.4, 0.9)	(-6.5, -4.3)	(-0.3, 2.0)	(38, 59)	(36, 62)	**
Glaucoma							
Superior Temporal	24	(-4.3, 1.5)	(-5.3, -3.2)	(0.5, 2.6)	(18, 52)	(19, 55)	**
Superior	24	(-3.1, 4.6)	(-4.5, -1.7)	(3.2, 6.0)	(23, 52)	(20, 54)	(28.9, 61.7)
Superior Nasal	24	(-4.4, 3.9)	(-5.9, -2.9)	(2.4, 5.4)	(28, 53)	(24, 57)	**
Inferior Nasal	24	(-5.0, 3.4)	(-6.6, -3.5)	(1.9, 4.9)	(17, 54)	(19, 58)	**
Inferior	24	(-2.8, 5.0)	(-4.3, -1.4)	(3.5, 6.4)	(14, 52)	(17, 54)	(23.2, 60.0)
Inferior Temporal	24	(-3.9, 3.1)	(-5.2, -2.7)	(1.8, 4.4)	(16, 54)	(18, 57)	**
Global Value	24	(-3.0, 2.6)	(-4.1, -2.0)	(1.5, 3.6)	(24, 51)	(22, 54)	**



Difference = SPECTRALIS – Manual

NFL: Nerve Fiber Layer. GCL: Ganglion Cell Layer

Estimated Clinical Range was derived per literature search. ** = range could not be derived per literature search due to grid differences.

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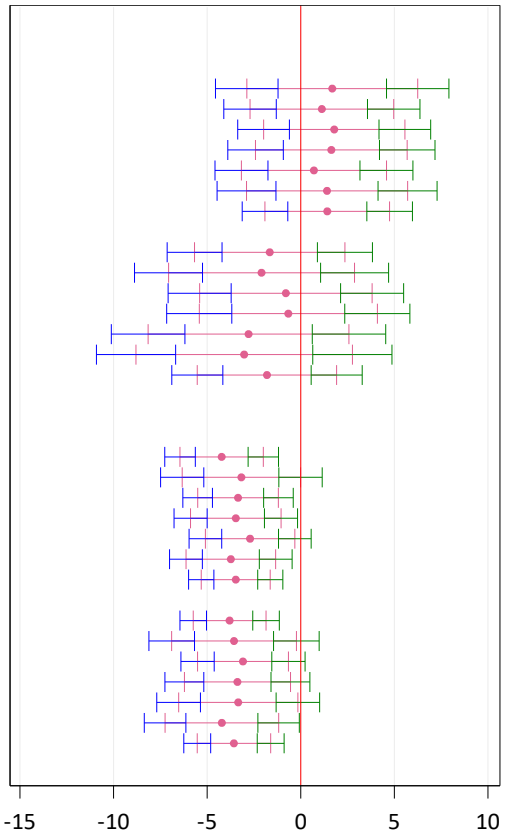
Figure 3 LOA Summary of Macular Grid IPL and GCC Parameters between SPECTRALIS and Manual Measurements, Agreement Analysis Population

Parameter (µm)	N	Limit of Agreement (LoA)	95% CI of Lower Limit of LoA	95% CI of Upper Limit of LoA	SPECTRALIS Range	Average Manual Range	Estimated Clinical Range
IPL							
Normal							
Superior Temporal	24	(-2.9, 6.2)	(-4.6, -1.2)	(4.6, 7.9)	(31, 46)	(34, 44)	**
Superior	24	(-2.7, 5.0)	(-4.1, -1.3)	(3.6, 6.4)	(32, 47)	(32, 45)	(34.3, 49.0)
Superior Nasal	24	(-2.0, 5.6)	(-3.4, -0.6)	(4.2, 6.9)	(31, 46)	(32, 43)	**
Inferior Nasal	24	(-2.4, 5.7)	(-3.9, -0.9)	(4.2, 7.2)	(30, 46)	(34, 43)	**
Inferior	24	(-3.2, 4.6)	(-4.6, -1.8)	(3.2, 6.0)	(31, 45)	(33, 44)	(34.5, 47.5)
Inferior Temporal	24	(-2.9, 5.7)	(-4.5, -1.3)	(4.1, 7.3)	(30, 47)	(33, 45)	**
Global Value	24	(-1.9, 4.7)	(-3.1, -0.7)	(3.5, 6.0)	(31, 46)	(33, 44)	**
Glaucoma							
Superior Temporal	24	(-5.7, 2.4)	(-7.1, -4.2)	(0.9, 3.8)	(23, 42)	(27, 39)	**
Superior	24	(-7.1, 2.9)	(-8.9, -5.2)	(1.1, 4.7)	(22, 41)	(28, 40)	(27.7, 46.9)
Superior Nasal	24	(-5.4, 3.8)	(-7.1, -3.7)	(2.1, 5.5)	(26, 44)	(30, 40)	**
Inferior Nasal	24	(-5.4, 4.1)	(-7.2, -3.7)	(2.4, 5.8)	(23, 42)	(27, 40)	**
Inferior	24	(-8.2, 2.6)	(-10.1, -6.2)	(0.6, 4.5)	(21, 41)	(26, 40)	(24.3, 45.1)
Inferior Temporal	24	(-8.8, 2.8)	(-10.9, -6.7)	(0.6, 4.9)	(20, 43)	(26, 41)	**
Global Value	24	(-5.5, 1.9)	(-6.9, -4.2)	(0.6, 3.3)	(25, 42)	(29, 39)	**
GCC							
Normal							
Superior Temporal	24	(-6.4, -2.0)	(-7.3, -5.6)	(-2.8, -1.2)	(82, 121)	(87, 124)	(81.2, 116.6)
Superior	24	(-6.3, -0.0)	(-7.5, -5.2)	(-1.2, 1.1)	(93, 133)	(94, 135)	(90.4, 135.2)
Superior Nasal	24	(-5.5, -1.2)	(-6.3, -4.7)	(-2.0, -0.4)	(92, 132)	(93, 136)	(100.8, 140.9)
Inferior Nasal	24	(-5.9, -1.1)	(-6.8, -5.0)	(-1.9, -0.2)	(89, 133)	(93, 136)	(97.4, 142.8)
Inferior	24	(-5.1, -0.3)	(-6.0, -4.2)	(-1.2, 0.6)	(93, 135)	(97, 138)	(86.9, 133.9)
Inferior Temporal	24	(-6.1, -1.3)	(-7.0, -5.3)	(-2.2, -0.5)	(89, 124)	(94, 126)	(82.2, 119.7)
Global Value	24	(-5.3, -1.6)	(-6.0, -4.6)	(-2.3, -1.0)	(89, 129)	(93, 132)	(91.5, 129.0)
Glaucoma							
Superior Temporal	24	(-5.7, -1.9)	(-6.5, -5.0)	(-2.6, -1.1)	(58, 113)	(62, 116)	(55.1, 115.8)
Superior	24	(-6.9, -0.2)	(-8.1, -5.7)	(-1.5, 1.0)	(59, 127)	(66, 130)	(59.9, 134.9)
Superior Nasal	24	(-5.5, -0.7)	(-6.4, -4.6)	(-1.5, 0.2)	(73, 124)	(77, 126)	(68.7, 140.6)
Inferior Nasal	24	(-6.2, -0.6)	(-7.3, -5.2)	(-1.6, 0.5)	(59, 120)	(61, 123)	(57.7, 136.3)
Inferior	24	(-6.5, -0.2)	(-7.7, -5.4)	(-1.3, 1.0)	(54, 118)	(57, 121)	(53.2, 128.7)
Inferior Temporal	24	(-7.2, -1.2)	(-8.4, -6.1)	(-2.3, -0.1)	(55, 121)	(58, 124)	(49.3, 114.1)
Global Value	24	(-5.5, -1.6)	(-6.3, -4.8)	(-2.3, -0.9)	(65, 117)	(69, 119)	(60.3, 124.2)



Difference = SPECTRALIS – Manual

IPL: Inner Plexiform Layer. GCC: Ganglion Cell Complex Layer (GCC=NFL+GCL+IPL)

Estimated Clinical Range was derived per literature search. ** = range could not be derived per literature search due to grid differences.

Precision

For Macular Grid GCL+IPL measurements, repeatability and reproducibility CV%s were better on SPECTRALIS than on Cirrus and were all < 2.8% on SPECTRALIS in all sectors and populations. For ETDRS Grid TRT measurements, repeatability and reproducibility CV%s were generally better on SPECTRALIS than on Cirrus and was < 2% on SPECTRALIS in all sectors and for all eye populations, except in the 1mm Central sector in eyes with Retinal Disease. The results suggest that SPECTRALIS' precision is generally similar or better compared to Cirrus for measurement of GCL+IPL thickness in the Macular Grid and TRT in the ETDRS Grid in all populations evaluated.

Of the remaining parameters measured using the Macular Grid on SPECTRALIS only, NFL had worse precision CV%s (≤ 7.601%) compared to other layers (GCL ≤ 4.797%, IPL ≤ 3.384%) as it was the thinnest layer evaluated; and for GCC [NFL+GCL+IPL], all repeatability and reproducibility CV%s were < 2.3%. Additionally, repeatability and reproducibility CV%s for TRT as measured via Macular Grid were all < 1% in all sectors and both eye populations evaluated. The results suggest that SPECTRALIS' precision is reasonable for these macular parameters, in both Normal eyes and eyes with Glaucoma.

SPECTRALIS and Cirrus precision results for repeatability and reproducibility are presented below in Table 1 for Macular Grid GCL+IPL and ETDRS Grid TRT.

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Table 1 Repeatability and Reproducibility SD and CV%, SPECTRALIS versus Cirrus

Eye Population	SPECTRALIS							Cirrus						
	# of	# of	Intercept	Repeatability		Reproducibility		# of	# of	Intercept	Repeatability		Reproducibility	
Parameter	Eyes	Scans	(µm)	SD (µm)	CV%	SD (µm)	CV%	Eyes	Scans	(µm)	SD (µm)	CV%	SD (µm)	CV%
Macular Grid Ganglion Cell Layer + Inner Plexiform Layer (GCL + IPL) Thickness, CSR Tables 9-32 & 9-33														
Normal Eyes														
Superior Temporal	24	216	87.008	1.487	1.709	1.643	1.889	25	222	79.837	4.828	6.047	4.859	6.086
Superior	24	216	91.004	1.248	1.372	1.283	1.410	25	222	80.639	4.361	5.408	4.382	5.434
Superior Nasal	24	216	91.666	1.150	1.255	1.316	1.435	25	222	82.582	4.054	4.909	4.088	4.951
Inferior Nasal	24	216	91.739	1.262	1.376	1.417	1.545	25	222	81.165	1.827	2.250	1.872	2.306
Inferior	24	216	89.566	1.544	1.724	1.669	1.864	25	222	79.880	1.257	1.574	1.301	1.628
Inferior Temporal	24	216	89.965	1.287	1.430	1.370	1.523	25	222	81.454	2.470	3.032	2.639	3.240
Global Value	24	216	90.151	0.585	0.649	0.733	0.813	25	222	80.950	2.766	3.417	2.786	3.442
Eyes with Glaucoma														
Superior Temporal	24	216	64.487	1.571	2.437	1.762	2.732	24	214	61.915	4.438	7.168	4.438	7.168
Superior	24	216	72.766	1.432	1.968	1.457	2.003	24	214	64.865	4.880	7.524	4.918	7.582
Superior Nasal	24	216	77.224	1.050	1.360	1.087	1.408	24	214	69.700	4.884	7.008	4.909	7.042
Inferior Nasal	24	216	74.909	1.110	1.482	1.280	1.709	24	214	66.451	2.181	3.282	2.192	3.299
Inferior	24	216	68.307	1.390	2.034	1.399	2.048	24	214	61.969	3.376	5.448	3.376	5.448
Inferior Temporal	24	216	62.066	1.489	2.399	1.550	2.498	24	214	60.607	2.947	4.862	3.016	4.976
Global Value	24	216	69.928	0.631	0.902	0.717	1.026	24	214	64.245	3.359	5.229	3.373	5.251

Repeatability SD = Square root of residual variance. Repeatability CV% = (Repeatability SD)/Intercept x 100%.

Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance. Reproducibility CV% = (Reproducibility SD)/Intercept x 100%.

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Table 1 Repeatability and Reproducibility SD and CV%, SPECTRALIS versus Cirrus

Eye Population	SPECTRALIS							Cirrus						
	# of	# of	Intercept	Repeatability		Reproducibility		# of	# of	Intercept	Repeatability		Reproducibility	
Parameter	Eyes	Scans	(µm)	SD (µm)	CV%	SD (µm)	CV%	Eyes	Scans	(µm)	SD (µm)	CV%	SD (µm)	CV%
ETDRS Grid Total Retinal Thickness (TRT), CSR Tables 9-35 & 9-36														
Normal Eyes														
1mm Central	24	216	267.162	2.470	0.925	2.979	1.115	25	222	254.151	5.833	2.295	5.846	2.300
3mm Superior	24	216	338.972	2.118	0.625	2.518	0.743	25	222	318.210	5.638	1.772	6.009	1.889
3mm Nasal	24	216	337.505	2.489	0.737	3.232	0.958	25	222	319.940	3.042	0.951	3.374	1.054
3mm Inferior	24	216	332.931	2.092	0.628	2.599	0.781	25	222	313.680	2.993	0.954	3.253	1.037
3mm Temporal	24	216	323.704	1.511	0.467	2.367	0.731	25	222	304.583	3.183	1.045	3.798	1.247
6mm Superior	24	216	298.509	2.453	0.822	2.787	0.934	25	222	276.284	2.896	1.048	3.294	1.192
6mm Nasal	24	216	312.060	1.768	0.566	2.114	0.678	25	222	293.190	1.564	0.533	2.213	0.755
6mm Inferior	24	216	285.935	2.260	0.790	2.616	0.915	25	222	265.480	3.081	1.160	3.713	1.398
6mm Temporal	24	216	280.579	2.600	0.927	3.165	1.128	25	222	258.388	2.082	0.806	2.779	1.076
Eyes with Retinal Disease														
1mm Central	24	216	273.884	8.682	3.170	14.665	5.354	24	205	256.679	4.374	1.704	4.700	1.831
3mm Superior	24	216	332.528	3.124	0.939	3.867	1.163	24	205	315.744	2.246	0.711	2.605	0.825
3mm Nasal	24	216	340.185	4.563	1.341	6.685	1.965	24	205	323.481	2.085	0.645	2.422	0.749
3mm Inferior	24	216	334.139	5.176	1.549	5.339	1.598	24	205	317.891	1.896	0.597	2.692	0.847
3mm Temporal	24	216	328.509	3.274	0.997	4.624	1.408	24	205	311.429	1.887	0.606	2.802	0.900
6mm Superior	24	216	293.032	2.658	0.907	3.097	1.057	24	205	277.784	1.689	0.608	1.978	0.712
6mm Nasal	24	216	305.884	2.482	0.812	2.893	0.946	24	205	291.872	1.381	0.473	1.865	0.639
6mm Inferior	24	216	283.218	2.699	0.953	3.444	1.216	24	204	267.354	2.489	0.931	3.375	1.262
6mm Temporal	24	216	286.616	2.676	0.934	3.855	1.345	24	205	269.941	2.094	0.776	2.554	0.946
Eyes with Glaucoma														
1mm Central	24	216	249.653	2.771	1.110	3.575	1.432	24	214	235.078	9.065	3.856	9.175	3.903
3mm Superior	24	216	312.921	1.537	0.491	2.025	0.647	24	214	294.271	6.758	2.296	6.847	2.327
3mm Nasal	24	216	318.616	2.215	0.695	2.757	0.865	24	214	301.655	3.410	1.130	3.761	1.247
3mm Inferior	24	216	307.185	1.861	0.606	2.281	0.742	24	214	288.483	6.165	2.137	6.165	2.137
3mm Temporal	24	216	298.282	1.847	0.619	2.608	0.874	24	214	280.004	4.939	1.764	5.312	1.897
6mm Superior	24	216	266.037	2.153	0.809	2.600	0.977	24	214	248.812	3.629	1.459	3.899	1.567
6mm Nasal	24	216	285.880	2.033	0.711	2.394	0.837	24	214	269.905	1.761	0.653	2.335	0.865
6mm Inferior	24	216	255.560	2.360	0.923	2.979	1.166	24	209	239.136	4.845	2.026	6.499	2.718
6mm Temporal	24	216	253.856	1.961	0.773	2.451	0.965	24	214	235.644	2.676	1.135	3.102	1.317

Repeatability SD = Square root of residual variance. Repeatability CV% = (Repeatability SD)/Intercept x 100%.

Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance. Reproducibility CV% = (Reproducibility SD)/Intercept x 100%.

Safety

There was one adverse event that occurred during the course of the study, which was determined not to be related to the study devices as the participant was never scanned.

CONCLUSION

The subject SPECTRALIS HRA+OCT and variants and the SPECTRALIS with Flex Module (software version 7.4) each have the same intended use, indications for use, and fundamental technological characteristics as their respective legally marketed predicate devices (K250868, K241163). The software and mechanical modifications described herein do not raise new or different questions of safety or effectiveness.

Based on the clinical study results, in which the tabletop SPECTRALIS HRA+OCT was compared to the reference device, the CIRRUS HD-OCT 5000 (K150977), and to manual segmentation of SPECTRALIS acquisitions for parameters unique to the SPECTRALIS device, it can be concluded that the subject SPECTRALIS HRA+OCT and its variants perform similarly to the reference device for measurement of macular layer thicknesses. For macular parameters provided by both devices, the results showed reasonable agreement with some systematic differences between devices that can be explained by grid size and layer segmentation differences. SPECTRALIS had generally similar or better precision as compared to Cirrus. Measurements are not interchangeable between different devices. Patients should be monitored with the same device model over time. For macular parameters provided by SPECTRALIS only, the results showed general agreement compared to manual segmentation results and reasonable precision values.

The study results support the substantial equivalence of the subject SPECTRALIS HRA+OCT and variants to the predicate SPECTRALIS HRA+OCT and variants (K250868).