October 11, 2024

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

Re: K241163
Trade/Device Name: SPECTRALIS with Flex Module
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO, MYC
Dated: April 26, 2024
Received: April 26, 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.

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,

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.

510(k) Number *(if known)*
K241163

Device Name
SPECTRALIS with Flex Module

Indications for Use *(Describe)*
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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

HEIDELBERG ENGINEERING

510(K) SUMMARY

Date Prepared September 09, 2024

SPONSOR/510(K) OWNER/ MANUFACTURER

Heidelberg Engineering GmbH
Max-Jarecki-Strasse 8
69115 Heidelberg, Germany
Telephone: +49 6221 / 64 63 0
Facsimile: +49 6221 / 64 63 62
Email: arianna.schoess.vargas@heidelbergengineering.com
Establishment Registration No.: 8043762

OFFICIAL CONTACT PERSON

Lena Sattler
Orasi Consulting, LLC.
226 1st Street
Bonita Springs, FL 34134
Telephone: (440) 554-3706
Facsimile: (866) 904-4315
E-mail: lena@orasiconsulting.com

COMMON/USUAL NAME

Optical Coherence Tomography

PROPRIETARY OR TRADE NAMES

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

HEIDELBERG ENGINEERING

PRIMARY PREDICATE DEVICE

SPECTRALIS HRA+OCT and variants (K223557), Heidelberg Engineering GmbH

SECONDARY PREDICATE DEVICE

Bioptigen ENVISU Spectral Domain Ophthalmic Imaging System (K120057)

INDICATIONS FOR USE

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

The Heidelberg Engineering SPECTRALIS with Flex Module is based on the predicate SPECTRALIS HRA+OCT consisting of an accessory device mount allowing imaging of patients in supine position. The SPECTRALIS with Flex Module is intended for visualization of the posterior segments of the human eye. The SPECTRALIS with Flex Module is using the identical technologies as the predicate SPECTRALIS tabletop configuration (K223557), i.e. it is a combination of a confocal laser-scanning ophthalmoscope (cSLO, the HRA portion) and a spectral-domain optical coherence tomographer (SD-OCT).

COMPARISON BETWEEN THE SUBJECT AND THE PREDICATE DEVICE

The modifications made to the SPECTRALIS HRA+OCT with the introduction of the optional accessory, the Flex Module do not change the applied technologies (OCT, cSLO) and the imaging modes of SPECTRALIS. The main differences between the SPECTRALIS with Flex Module and the predicate tabletop configuration cleared in K223557 are that the SPECTRALIS with Flex Module is for visualization only and allows imaging of supine patients. The imaging of supine patients expands the patient profile by including patients unable to follow simple instructions (e.g., unconscious, pediatrics). The tabletop SPECTRALIS with headrest requires upright sitting and thus awake patients able to follow simple instructions and provides measurements and includes reference databases.

The application of a non-contact ophthalmic OCT device for imaging of conscious or unconscious pediatrics and adults in supine position is also supported by the secondary predicate device, the Bioptigen ENVISU Imaging System which was cleared in K120057. The Bioptigen ENVISU device consists of a handheld, lightweight camera (scan head) which can be also mounted and provides a mobile cart for the optical engine and power supply. Due to the principle of using a handheld camera the physical dimensions and layout is different for the Bioptigen ENVISU and the subject and predicate SPECTRALIS devices, respectively.

Accordingly, due to its use for imaging supine patients, the mobile Flex Module has a different layout as well as larger dimensions and weight than the fixed camera mount

used for the tabletop. All other components to be used with the SPECTRALIS device are unchanged for the SPECTRALIS with Flex Module and are similar for the Bioptigen ENVISU. The SPECTRALIS with Flex Module uses an identical camera, the same power supply and touch panel as the predicate tabletop SPECTRALIS.

The Substantial Equivalence summary tables below illustrate the comparisons of the subject SPECTRALIS to the predicate devices.

HEIDELBERG ENGINEERING

INDICATIONS FOR USE STATEMENT CHART

Subject Device **SPECTRALIS with Flex Module** **(K241163)**	**Primary Predicate Device** **SPECTRALIS** **(K223557)**	**Secondary Predicate Device** **Bioptigen ENVISU Spectral Domain Ophthalmic Imaging System (K120057)**	**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 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	Bioptigen ENVISU^{Tm} Spectral Domain Ophthalmic Imaging System (SDOIS) is intended to acquire, process, display and save depth-resolved images of ocular tissue microstructure using Spectral Domain Optical Coherence Tomography (SD-OCT). The ENVISU SDOIS is indicated for use as an aid in the diagnosis of physiologic and pathologic conditions of the eye through non-contact optical imaging. Imaging of the various tissues of the eye is supported through the use of interchangeable lenses. It is indicated for use on patient populations from premature and neonatal infants to adult, and is suitable for patients ambulatory or confined. The system is indicated for use in upright or supine imaging, handheld or mounted, and is suited for imaging patients under anesthesia.	K223557: Different (measurements, upright patients) K120057: Similar (visualization only, pediatric and supine patients)

	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)		

TECHNOLOGICAL CHARACTERISTICS COMPARISON CHART

Feature	Subject Device SPECTRALIS with Flex Module	Primary Predicate Device SPECTRALIS (K223557)	Secondary Predicate Device Bioptigen ENVISU Spectral Domain Ophthalmic Imaging System (K120057)	Same, similar or different
Device classification name	Optical Coherence Tomographer (OCT)	Optical Coherence Tomographer (OCT)	Optical Coherence Tomographer (OCT)	K223557, K120057: 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)	Spectral-Domain Optical Coherence Tomograph (OCT)	K223557: Same K120057: Similar (OCT only)
Physical Dimensions	Laser scanning camera: 235 mm x 100 mm x 205 mm Weight camera head: 5.6 kg Flex Module: Height 1690 plus 300 swivel range in mm, width 1467 mm maximum Operation panel: 170 mm x 185 mm x 100 mm	Laser scanning camera: 235 mm x 100 mm x 205 mm Weight camera head: 5.6 kg Camera Mount: 470 mm x 325 mm x 550 mm Operation panel: 170 mm x 185 mm x 100 mm	OCT Scan head: 170 mm high x 80 mm wide x 230 mm long (incl. lens) Scan head weight: 1.6 kg Cart footprint: Height 953 mm alone, 1549 mm with monitor, width 787 mm, depth 559 mm	K223557: Different K120057: Different: The Flex Module for supine patients has other dimensions than the predicate tabletop mount with headrest (K223557). The predicate Bioptigen (K120057) is a handheld

Feature	Subject Device SPECTRALIS with Flex Module	Primary Predicate Device SPECTRALIS (K223557)	Secondary Predicate Device Bioptigen ENVISU Spectral Domain Ophthalmic Imaging System (K120057)	Same, similar or different
	Power supply including spectrometer: 180 mm x 335 mm x 165 mm	Power supply including spectrometer: 180 mm x 335mm x 165 mm		mountable camera with a mobile cart.
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, 488nm 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, 488nm Indocyanine green angiography: diode laser, 786 nm Optical coherence tomography: superluminescence diode, 840 nm to 920 nm (weighted average 880 nm)	No Laser Scanning (cSLO) available Optical coherence tomography: superluminescence diode, 760 nm to 930 nm (860 nm)	K223557: Same (cSLO) K120057: N/A (cSLO) K223557: Same (OCT) K120057: Similar (OCT)
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	Class 1 LED	K223557, K120057: Same
Lateral optical resolution (OCT)	14 µm (standard objective), 24 µm (WFO2)	14 µm (standard objective), 24 µm (WFO2)	Retina: 20 µm in tissue	K223557: Same K120057: Similar
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	Not known	K223557: Same K120057: N/A
Optical depth resolution (OCT)	7 µm	7 µm	≤ 6 µm (High Resolution, HR) < 4 µm (Very High Resolution, VHR)	K223557: Same K120057: Similar
OCT acquisition speed (Maximum A-scan rate)	40 kHz (Firewire), 85 kHz (Thunderbolt)	40 kHz (Firewire), 85 kHz (Thunderbolt)	32 kHz	K223557: Same K120057: Similar

Feature	Subject Device SPECTRALIS with Flex Module	Primary Predicate Device SPECTRALIS (K223557)	Secondary Predicate Device Bioptigen ENVISU Spectral Domain Ophthalmic Imaging System (K120057)	Same, similar or different
OCT acquisition modes	Standard, Enhanced Depth Imaging (EDI), Enhanced Vitreous Imaging (EVI)	Standard, Enhanced Depth Imaging (EDI), Enhanced Vitreous Imaging (EVI)	N/A, no different acquisition modes available	K223557: Same K120057: N/A
cSLO imaging modes for artifact suppression	Reflectance (R), Cross-Polarization (XP), Widefield Reflectance (WR)	Reflectance (R), Cross-Polarization (XP), Widefield Reflectance (WR)	N/A, no cSLO imaging available	K223557: Same K120057: N/A
OCTA scan types	Volume OCTA, Scout OCTA, DART Volume OCTA, DART Line	Volume OCTA, Scout OCTA, DART Volume OCTA, DART Line	N/A, no OCT-Angiography available	K223557: Same K120057: N/A
Lateral field of view (SLO)	SO (standard objective): 15°x15° to 30 x30° HMM: 8°x8° WFO2: 25°x25° to Ø 55° UWF Objective: 51°x 1° to Ø102°	SO (standard objective): 15°x15° to 30 x30° HMM: 8°x8° WFO2: 25°x25° to Ø 55° UWF Objective: 51°x 1° to Ø102°	N/A, no cSLO imaging available	K223557: Same K120057: N/A
Lateral field of view (OCT)	Standard objective lens: 15°-30°, WFO2: 25°-55°	Standard objective lens: 15°-30°, WFO2: 25°-55°	Posterior retina: 70°	K223557: Same K120057: Different
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)	N/A, no cSLO imaging available	K223557: Same K120057: N/A
Lateral digital resolution (OCT)	Standard and WFO2 objective lenses: same as SLO	Standard and WFO2 objective lenses: same as SLO	Posterior retina: 11 µm	K223557: Same K120057: Similar
Axial digital image size	496 pixels	496 pixels	512 pixels or 1024 pixles	K223557: Same K120057: Similar
Digital axial resolution (pixel size OCT)	3.9 µm	3.9 µm	1.6 µm or 2.4 µm (1024 pixels)	K223557: Same K120057: Similar
Scan depth	1.9 mm	1.9 mm	1.7 mm (High Resolution) or 2.5 mm (Very High Resolution)	K223557: Same K120057: Different
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	Yes, OCT volume scan	K223557, K120057: Same

Feature	Subject Device SPECTRALIS with Flex Module	Primary Predicate Device SPECTRALIS (K223557)	Secondary Predicate Device Bioptigen ENVISU Spectral Domain Ophthalmic Imaging System (K120057)	Same, similar or different
Measurements	Measured data points are not displayed	Measured data points are displayed	No measurements	K223557: Different K120057: Same (visualization only)
Image compression	No	No	No	K223557, K120057: Same
Display of the data	Images are visible on a standard PC-Monitor	Images are visible on a standard PC-Monitor	Images are visible on a standard PC-Monitor	K223557, K120057: 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	• Fixed camera mount with headrest and joystick • Optical camera head • Power supply and spectrometer unit • Touch panel • Computer with monitor, keyboard, mouse, and printer	• Mobile cart • Handheld or mounted scanning (camera) head • Power supply, optical engine (spectromerter, LED light) • Computer with monitor	K223557: Different (tabletop mount) Same (other components) K120057: Different (handheld camera, mobile cart), Similar (other components)
Patient Profile	• No special assumptions about the ethnicity, body weight, biological sex, or age of the patient • Patients in supine position • Patients, able to follow simple instructions including pediatrics and adults • Patients not able to follow simple instructions (unconscious and anesthetized patients patients) including pediatrics and adults	• No special assumptions about the ethnicity, body weight, biological sex, or age of the patient • Patients sitting upright in front of the device • Awake patients, able to follow simple instructions including pediatrics and adults	• Pediatric patients • Adult patients • Supine patients • Upright sitting patients • Any patient that finds it difficult to sit upright or where it is clinically preferable to image without the constraint of a chin • Anesthetized patients	K223557: Different (awake, upright) K120057: Similar (pediatric, supine)
Thunderbolt Interface	Thunderbolt-3 Interface	Thunderbolt-3 Interface	N/A (not known)	K223557: Same K120057: N/A
Flammability of the materials	The metal housing of the device prevents flammability	The metal housing of the device prevents flammability	The metal housing of the device prevents flammability	K223557: Same K120057: Similar

HEIDELBERG ENGINEERING

Feature	Subject Device SPECTRALIS with Flex Module	Primary Predicate Device SPECTRALIS (K223557)	Secondary Predicate Device Bioptigen ENVISU Spectral Domain Ophthalmic Imaging System (K120057)	Same, similar or different
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	13 mm working distance (posterior retina)	K223557: Same K120057: Different
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;	N/A	K223557: Same K120057: N/A
Anterior Segment Module (ASM) Objective Lens	Not available	12 mm working distance, 65 mm length, 49.5 mm outer diameter, 30° field of view, not used for measurements	15 mm,17 mm or 20 mm working distance	K223557: Diferent K120057: Different
Wide Field Objective (WFO2)	10 mm working distance, 46 mm length, 49 mm outer diameter; 55° field of view; not used for measurements; WFO2 has the same design and optical layout as WFO, but an improved anti-reflective coating	10 mm working distance, 46 mm length, 49 mm outer diameter; 55° field of view; not used for measurements; WFO2 has the same design and optical layout as WFO, but an improved anti-reflective coating	N/A	K223557: Same K120057: N/A
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	N/A	K223557: Same K120057: N/A
Objective lens protection caps	For standard and widefield objective lens	N/A	N/A	K223557, K120057: Different
Supported Operating System	Windows 10, Windows 11	Windows 10, Windows 11	Windows XP	K223557: Same K120057: Similar

HEIDELBERG ENGINEERING

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, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Documentation regarding cybersecurity was submitted as recommended by FDA's Guidance for Industry and FDA Staff, "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 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 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 SPECTRALIS.

CLINICAL PERFORMANCE TESTING

One clinical, prospective, observational case study (S-2018-3) was performed at a single clinical site, located in the United States, to collect data in support of a 510(k) submission to obtain marketing clearance of the SPECTRALIS with Flex Module, where the Flex Module is an optional accessory to the SPECTRALIS device consisting of an adjustable camera arm mounted on a wheeled instrument base to enable in-vivo imaging in the supine position for visualization only. The predicate used in the study was the cleared SPECTRALIS HRA+OCT (and variants) with a tabletop-mounted instrumentation base.

There were two study populations, the Adult Normal Eyes population (those without posterior segment abnormalities) and the Adult Posterior Segment Abnormality Eyes population (those with structural and/or vascular posterior segment abnormalities). Randomization was performed for eye selection (if applicable), acquisition type (i.e. OCT and/or OCTA) order (if applicable) and device order. The first acceptable acquisition of each applicable acquisition type (OCTA and/or Standard OCT) from each device was submitted for grading. The IR cSLO image extracted from the first acquisition type for each device (either OCTA or Standard OCT based on randomization order, if applicable) was also separately submitted for grading.

Three independent readers from a reading center graded the IR cSLO, OCT and OCTA images on overall image quality, and for OCT and OCTA only, the readers assessed visibility of key anatomic structures, and identified the presence of abnormalities (or lack

thereof). The analyses were based on the grading results from the effectiveness analysis population, which included all eligible study eyes with an image result for at least one acquisition from the investigational device (SPECTRALIS with Flex) from the reading center.

Data were collected for agreement analysis to show substantial equivalence between the investigational study device and stated predicate. Eighty-eight (88) subjects signed the informed consent form and were enrolled in the study. Of the 88 subjects enrolled, 84 completed the study and 4 were discontinued (2 subjects were unable to complete required scans, 1 subject withdrew voluntarily and for 1 subject there was a device deficiency that occurred prior to attempting any imaging). There were 9 subjects (5 Normal, 4 Posterior Segment Abnormality) who completed the study but subsequently identified as having failed to meet inclusion/exclusion criteria during study monitoring. One Normal subject who was unable to complete required scans was included in the effectiveness population as they had acceptable scans from both devices on at least one acquisition type.

The safety population consisted of 87 subjects, 30 Normal subjects and 57 Posterior Segment Abnormality subjects. No adverse events occurred during the course of the study. The effectiveness population consisted of 25 Normal subjects and 51 Posterior Segment Abnormality subjects. The effectiveness population count differed for each image type based on the Abnormalities of Interest specified and availability of acceptable acquisitions.

All 76 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 Posterior Segment Abnormality population.

The mean age was 57.3 ± 19.2 years overall, with the Posterior Segment Abnormality population subjects being older. The study population had more female subjects (59.2%) than male (40.8%). A majority (96.1%) did not identify as Hispanic or Latino, while 80% identified as White, 18.4% identified as Black/African American and 2.6% identified as Asian.

The Normal population had normal (or non-clinically significant) eye examination findings for all study eyes, while 100% of the Posterior Segment Abnormality population study eyes had abnormal (or clinically significant) retina, macular and/or periphery eye examination findings. Posterior Segment Abnormality population study eyes also had abnormal (or clinically significant) ophthalmoscopy findings for 13.8% (undilated) to 22.7% (dilated) of eyes when assessing the optic nerve, and 34.5% (undilated) to 36.4% (dilated) of eyes when assessing the vitreous.

The results of this study found that, based on the proportion of images graded better than Poor on consensus in the effectiveness population in All Eyes, 100% of OCT, 100% of IR cSLO, and 97.2% of OCTA images from the investigational SPECTRALIS with Flex were assessed as having overall image quality sufficient to assess the clinically relevant content. Additionally, in All Eyes, clinically acceptable visualization of key anatomic structures on the investigational SPECTRALIS with Flex was achieved on OCT in 100% of assessments, and on OCTA in 94.4% to 97.2% of assessments. In general, the results

demonstrate that the investigational SPECTRALIS with Flex images provide similar visualization as compared to the predicate SPECTRALIS.

For identification of pre-specified abnormalities, the agreement rates (based on the abnormalities identified by the reading center on the predicate, percentage of eyes with the same result on the investigational device) for all study populations indicate that the predicate and investigational device have similar outcomes for detecting structural abnormalities on OCT (agreement rate ≥ 84.3%) and vascular abnormalities on OCTA (agreement rate ≥ 85.1%). Similarly, negative percent agreement (NPA) was also high in All Eyes, with NPA at least 87.8% on OCT and at least 92.6% on OCTA for all pre-specified abnormalities. Positive percent agreement (PPA) for All Eyes was at least 75% for all pre-specified abnormalities on OCT and OCTA with more than 2 cases identified on the predicate. The results are similar between the investigational SPECTRALIS with Flex and the predicate SPECTRALIS, indicating that the ability to identify each pre-specified abnormality is similar between the devices.

Summary:

The results of this study show that overall image quality for OCT, OCTA and IR cSLO, and visibility of key anatomic structures for OCT and OCTA, are similar between the predicate SPECTRALIS and investigational SPECTRALIS with Flex in all study populations. Additionally, outcomes are similar between the predicate and investigational devices for identification of each abnormality seen on the investigational device when compared to the predicate. There were also no adverse events that occurred. Therefore, the study results support safety of the investigational SPECTRALIS with Flex and substantial equivalence between the predicate SPECTRALIS and investigational SPECTRALIS with Flex Module with regards to image quality, visibility of key anatomic structures, and identification of structural and vascular abnormalities.

LITERATURE REVIEW

The results of a systematic literature review showed that SPECTRALIS with Flex Module is effective and safe for ophthalmic imaging of the posterior segment in pediatric conscious or unconscious patients in the supine position.

CONCLUSION

The subject SPECTRALIS with Flex Module uses the same imaging technologies as the legally marketed SPECTRALIS (K223557). The results of the non-clinical performance testing demonstrate that the SPECTRALIS with Flex Module functions as intended. The outcome of the clinical performance testing supports substantial equivalence to the subject SPECTRALIS with Flex Module and for the predicate SPECTRALIS tabletop configuration. Furthermore, the results of the systematic literature review provide evidence for the safe and effective use of SPECTRALIS with Flex Module in pediatric conscious or unconscious patients. The application of a non-contact ophthalmic OCT device for supine and pediatric patients is also supported by the secondary predicate device, the Bioptigen ENVISU Imaging System (K120057). The SPECTRALIS with Flex Module shares the patient profile with Bioptigen ENVISU which includes conscious or unconscious pediatrics and adults in the supine position.

The non-clinical and clinical performance testing as well as the outcome of the literature review demonstrate that the subject SPECTRALIS device is as safe, as effective, and thus substantially equivalent to the predicate devices.