May 17, 2024

Carl Zeiss Meditec Inc
Tanesha Bland
Senior Regulatory Affairs Specialist- US SSC
5300 Central Parkway
Dublin, California 94568

Re: K233933
Trade/Device Name: CIRRUS™ HD-OCT Model 6000
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO
Dated: April 3, 2024
Received: April 8, 2024

Dear Tanesha Bland:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elvin Y. Ng -S

Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K233933

Device Name

CIRRUS™ HD-OCT Model 6000

Indications for Use *(Describe)*

The CIRRUS™ HD-OCT is a non-contact, high resolution tomographic and biomicroscopic imaging device. It is indicated for in-vivo viewing, axial cross-sectional, and three-dimensional imaging and measurement of anterior and posterior ocular structures, including cornea, retina, retinal nerve fiber layer, ganglion cell plus inner plexiform layer, macula, and optic nerve head.

The CIRRUS™ HD-OCT Reference Database is a quantitative tool used for the comparison of retinal nerve fiber layer thickness, macular thickness, ganglion cell plus inner plexiform layer thickness, and optic nerve head measurements to a database of healthy subjects.

CIRRUS™ HD-OCT AngioPlex angiography is indicated as an aid in the visualization of vascular structures of the retina and choroid.

The CIRRUS™ HD-OCT is indicated for use as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, macular holes, cystoid macular edema, diabetic retinopathy, age-related macular degeneration, and glaucoma.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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In accordance with 21 CFR 807.92 the 510(k) Summary for the CIRRUS Model 6000 RDB is provided below.

1. SUBMITTER

Applicant:	Carl Zeiss Meditec Inc 5300 Central Parkway Dublin, CA 94568 USA
Applicant Contact Name	Vidita Desai Senior Regulatory Affairs Specialist Carl Zeiss Meditec, Inc. 5300 Central Parkway | Dublin, CA 94568 Mobile:(925) 413-1644 E-mail: vidita.desai@zeiss.com (preferred)
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Secondary Correspondent	Maria Golovina, MS MBA Head of Regulatory Affairs – USA Carl Zeiss Meditec USA Inc. 5300 Central Parkway, Dublin CA USA 94568 Mobile: 925.216.1078 Email:Maria.Golovina@zeiss.com (preferred)
Date Prepared:	May 3, 2024

2. SUBJECT DEVICE

Device Trade Name:	CIRRUS HD-OCT Model 6000
Classification:	21CFR886.1570 Optical Coherence Tomography (OCT)
Regulatory Class:	II
Product Code:	OBO

3. PREDICATE DEVICE

Predicate Device:	CIRRUS HD-OCT Model 6000 (K222200)
Classification:	21CFR886.1570 Optical Coherence Tomography (OCT)
Regulatory Class:	II
Product Code:	OBO
Reference Device:	CIRRUS HD-OCT Model 500, 5000 (K181534)
Classification:	21CFR886.1570 Optical Coherence Tomography (OCT)
Regulatory Class:	II
Product Code:	OBO

4. DEVICE DESCRIPTION

The subject device is a computerized instrument that acquires and analyses cross-sectional tomograms of anterior and posterior ocular structures (including cornea, retina, retinal nerve fiber layer, macula, and optic disc). It employs non-invasive, non-contact, low-coherence interferometry to obtain these high-resolution images. CIRRUS 6000 has a 100kHz scan rate for all structural and angiography scans.

The subject device uses the same optical system, architecture, and principle of operation as the previously cleared CIRRUS 6000 (K222200) except for the reference database functionality.

The subject device contains a newly acquired reference database which was collected on devices cleared on K222200. This study data compares macular thickness, ganglion cell thickness, optic disc and RNFL measurements to a reference range of healthy eyes as guided by the age of the patient and /or optic disc size. Reference database outputs are available on Macular Cube 512x128, Macular Cube 200x200, and Optic Disc Cube 200x20 scan patterns. All other technical specifications have remained the same as the predicate K222200.

5. INDICATIONS FOR USE

The CIRRUS™ HD-OCT is a non-contact, high resolution tomographic and biomicroscopic imaging device. It is indicated for in-vivo viewing, axial cross-sectional, and three-dimensional imaging and measurement of anterior and posterior ocular structures, including cornea, retina, retinal nerve fiber layer, ganglion cell plus inner plexiform layer, macula, and optic nerve head.

The CIRRUS™ HD-OCT Reference Database is a quantitative tool used for the comparison of retinal nerve fiber layer thickness, macular thickness, ganglion cell plus inner plexiform layer thickness, and optic nerve head measurements to a database of healthy subjects.

CIRRUS™ HD-OCT AngioPlex angiography is indicated as an aid in the visualization of vascular structures of the retina and choroid.

The CIRRUS™ HD-OCT is indicated for use as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, macular holes, cystoid macular edema, diabetic retinopathy, age-related macular degeneration, and glaucoma.

6. SUBSTANTIAL EQUIVALENCE TO PRIMARY PREDICATE

Table 1. Subject to Predicate Device Comparison Table – Indications for Use

Device	Subject Device -CIRRUS 60000 with RDB	Predicate Device – CIRRUS 6000	Reference Device – CIRRUS 5000 (K181534)	Equivalency Analysis
Indications for Use	CIRRUS™ HD-OCT is a non-contact, high resolution tomographic and biomicroscopic imaging device. It is indicated for in-vivo viewing, axial cross-sectional, and three-dimensional imaging and measurement of anterior and posterior ocular structures, including cornea, retina, retinal nerve fiber layer, ganglion cell plus inner plexiform layer, macula, and optic nerve head. CIRRUS™ HD-OCT Reference Database is a quantitative tool used for the comparison of retinal nerve fiber layer thickness, macular thickness, ganglion cell plus inner plexiform layer thickness, and optic nerve head measurements to a database of healthy subjects.	CIRRUS HD-OCT is a non-contact, high resolution tomographic and biomicroscopic imaging device intended for in-vivo viewing, axial cross-sectional, and three-dimensional imaging of anterior and posterior ocular structures. The device is indicated for visualizing and measuring anterior and posterior ocular structures, including cornea, corneal epithelium, retina, retinal nerve fiber layer, ganglion cell plus inner plexiform layer, macula, and optic nerve head. CIRRUS AngioPlex OCT Angiography with is indicated as an aid in the visualization of vascular structures of the retina and choroid.	CIRRUS HD-OCT is a non-contact, high resolution tomographic and biomicroscopic imaging device intended for in-vivo viewing, axial cross-sectional, and three-dimensional imaging of anterior and posterior ocular structures. The device is indicated for visualizing and measuring anterior and posterior ocular structures, including cornea, corneal epithelium, retina, retinal nerve fiber layer, ganglion cell plus inner plexiform layer, macula, and optic nerve head. The CIRRUS normative databases are quantitative tools indicated for the comparison of retinal nerve fiber layer thickness, macular thickness, ganglion cell plus inner plexiform	Identical to the reference device.

Device	Subject Device -CIRRUS 60000 with RDB	Predicate Device – CIRRUS 6000	Reference Device – CIRRUS 5000 (K181534)	Equivalency Analysis
	CIRRUS™ HD-OCT AngioPlex angiography is indicated as an aid in the visualization of vascular structures of the retina and choroid. CIRRUS™ HD-OCT is indicated for use as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, macular holes, cystoid macular edema, diabetic retinopathy, age-related macular degeneration, and glaucoma.	CIRRUS HD-OCT is indicated as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, macular holes, cystoid macular edema, diabetic retinopathy, age-related macular degeneration, and glaucoma.	layer thickness, and optic nerve head measurements to a database of normal subjects. CIRRUS AngioPlex OCT Angiography with is indicated as an aid in the visualization of vascular structures of the retina and choroid. CIRRUS HD-OCT is indicated as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, macular holes, cystoid macular edema, diabetic retinopathy, age-related macular degeneration, and glaucoma.	

Table 2. Subject to Predicate Device Comparison Table – Technical Characteristics

Device	CIRRUS™ HD-OCT 6000 v. 11.7 Subject Device	CIRRUS™ HD-OCT 6000 Predicate Device (K222200)	Reference Device – CIRRUS 5000 (K181534)	Analysis
Device Classification Name	Tomography, Optical Coherence	Tomography, Optical Coherence	Tomography, Optical Coherence	Identical
Generic/ Common Name	Optical Coherence Tomography (OCT)	Optical Coherence Tomography (OCT)	Optical Coherence Tomography (OCT)	Identical
Classification Product Code	OBO	OBO	OBO	Identical
Class	II	II	II	Identical
Technology	Spectral Domain (Spatially encoded Frequency Domain and Fourier Domain Principle)	Spectral Domain (Spatially encoded Frequency Domain and Fourier Domain Principle)	Spectral Domain (Spatially encoded Frequency Domain and Fourier Domain Principle) OCT	Identical

	OCT	OCT		
Illumination Sources used in Instrument	Light Emitting Diode 700 nm – Iris Viewer LSO Super Luminescent Diode 750 nm OCT Super Luminescent Diode 840 nm	Light Emitting Diode 700 nm – Iris Viewer LSO Super Luminescent Diode 750 nm OCT Super Luminescent Diode 840 nm	Light Emitting Diode 700 nm – Iris Viewer LSO Super Luminescent Diode 750 nm OCT Super Luminescent Diode 840 nm	Identical
Models	6000	6000	5000	Identical to the predicate device.
	OCT IMAGING			
Methodology	Spectral domain OCT (SD-OCT)	Spectral domain OCT (SD-OCT)	Spectral domain OCT (SD-OCT)	Identical
OCT Optical Source	OCT Super Luminescent Diode, 840 nm wavelength	OCT Super Luminescent Diode, 840 nm wavelength	OCT Super Luminescent Diode, 840 nm wavelength	Identical
Optical Power	1200 µW at the cornea +/- 300 µW (0.9 - 1.5 mW) at the cornea.	1200 µW at the cornea +/- 300 µW (0.9 - 1.5 mW) at the cornea.	< 775 µW at the cornea	Identical to the predicate device.
Scan Speed	100,000 A-scans per second	100,000 A-scans per second	27,000 A-scans per second *68,000 A-scans per second only for OCT Angiography*	Identical to the predicate device.
Axial Scan Depth (Max)- Retina	• 2.9 mm for 12 mm 1 Line 100x HD Raster, HD Angio 8x8, Angio 8x8, and Angiography 12x12 • 2.0 mm for all other scans	• 2.9 mm for 12 mm 1 Line 100x HD Raster, HD Angio 8x8, Angio 8x8, and Angiography 12x12 • 2.0 mm for all other scans	2.0 mm	Identical to the predicate device.
Axial Scan Depth (Max)- Retina	2.0 mm (in tissue), 1024 pixels per A-scans for all other scan except for the ones listed above	2.0 mm (in tissue), 1024 pixels per A-scans for all other scan except for the ones listed above	2.0 mm (in tissue), 1024 pixels per A-scans.	Identical

Axial Scan Depth (Max) –Anterior Segment	2.0 mm (Anterior 5-Line Raster) – 1024 points2.0 mm (Anterior Segment Cube) – 1024 points 5.8 mm (Anterior Chamber) – 2048 points 2.9 mm (Wide Angle-to-Angle) – 1024 points 2.9 mm (HD Angle) – 1024 points 2.0 mm (HD Cornea) – 1024 points 2.0 mm (Pachymetry) – 1024 points	2.0 mm (Anterior 5-Line Raster) – 1024 points2.0 mm (Anterior Segment Cube) – 1024 points 5.8 mm (Anterior Chamber) – 2048 points 2.9 mm (Wide Angle-to-Angle) – 1024 points 2.9 mm (HD Angle) – 1024 points 2.0 mm (HD Cornea) – 1024 points 2.0 mm (Pachymetry) – 1024 points	2.0 mm (Anterior 5-Line Raster) – 1024 points2.0 mm (Anterior Segment Cube) – 1024 points 5.8 mm (Anterior Chamber) – 2048 points 2.9 mm (Wide Angle-to-Angle) – 1024 points 2.9 mm (HD Angle) – 1024 points 2.0 mm (HD Cornea) – 1024 points 2.0 mm (Pachymetry) – 1024 points	Identical
External Anterior Segment Lens	Anterior Chamber Lens Cornea Lens	Anterior Chamber Lens Cornea Lens	Anterior Chamber Lens Cornea Lens	Identical
Transverse Scan Range (Lateral range in degrees) Retina	10° x 0° on retina (Minimum) 42° x 42° on retina (Maximum)	10° x 0° on retina (Minimum) 42° x 42° on retina (Maximum	10° x 0° on retina (Minimum) 31° x 31° on retina (Maximum)	Identical to the predicate device.
Transverse Scan Range –Anterior Segment	3 mm (Minimum) 15 mm (Maximum)	3 mm (Minimum) 15 mm (Maximum)	3 mm (Minimum) 15 mm (Maximum)	Identical
Axial Resolution	5 µm (in tissue)	5 µm (in tissue)	5 µm (in tissue)	Identical
Transverse Resolution – Retina	≤ 15 µm (in tissue)	≤ 15 µm (in tissue)	≤ 15 µm (in tissue)	Identical
Transverse Resolution – Anterior Segment	20 µm (in tissue) 20 µm @ 6mm FOV 25 µm @ 9mm FOV	20 µm (in tissue) 20 µm @ 6mm FOV 25 µm @ 9mm FOV	20 µm (in tissue) 20 µm @ 6mm FOV	Identical

	45 µm @ 15mm FOV	45 µm @ 15mm FOV	25 µm @ 9mm FOV 45 µm @ 15mm FOV	
Scan patterns Non-angiography	Line, circle, crosshair, raster (a series of closely spaced lines, aka cube scan), radial scans and combinations of the above.	Line, circle, crosshair, raster (a series of closely spaced lines, aka cube scan), radial scans and combinations of the above.	Line, circle, crosshair, raster (a series of closely spaced lines, aka cube scan), radial scans and combinations of the above.	Identical
Scan types Non-angiography	Macular Cube 512 x 128 = 6 mm x 6 mm	Macular Cube 512 x 128 = 6 mm x 6 mm	Macular Cube 512 x 128 = 6 mm x 6 mm	Identical
	Macular Cube 200 x 200 = 6 mm x 6 mm	Macular Cube 200 x 200 = 6 mm x 6 mm	Macular Cube 200 x 200 = 6 mm x 6 mm	Identical
	Optic Disc Cube 200 x 200 = 6 mm x 6 mm	Optic Disc Cube 200 x 200 = 6 mm x 6 mm	Optic Disc Cube 200 x 200 = 6 mm x 6 mm	Identical
	Not available	Not available	5-Line Raster	Identical to the predicate device.
	HD (high-definition) Raster - HD 1 Line 100x (2.9 mm depth and up to 12 mm in length) - HD 21 Line - HD Radial - HD Cross - HD 5-Line Raster	HD (high-definition) Raster - HD 1 Line 100x (2.9 mm depth and up to 12 mm in length) - HD 21 Line - HD Radial - HD Cross - HD 5-Line Raster	HD (high-definition) Raster - HD 1 Line 100x (2.0 mm depth and up to 9 mm in length) - HD 21 Line - HD Radial - HD Cross HD 5-Line Raster	Identical to the predicate device.
	Anterior Segment Cube 512 x 128	Anterior Segment Cube 512 x 128	Anterior Segment Cube 512 x 128	Identical

	Anterior Segment 5-Line Raster	Anterior Segment 5-Line Raster	Anterior Segment 5-Line Raster	Identical
	HD Angle	HD Angle	HD Angle	Identical
	Anterior Chamber	Anterior Chamber	Anterior Chamber	Identical
	Wide Angle-to-Angle	Wide Angle-to-Angle	Wide Angle-to-Angle	Identical
	HD Cornea	HD Cornea	HD Cornea	Identical
	Pachymetry	Pachymetry	Pachymetry	Identical
OCT Angiography scans	**Scans:**	**Scans:**	**Scans:**	**Scans:**
	AngioPlex 3x3 mm scan	AngioPlex 3x3 mm scan	AngioPlex 3x3 mm scan	Identical
	AngioPlex 6x6 mm scan	AngioPlex 6x6 mm scan	AngioPlex 6x6 mm scan	Identical
	AngioPlex 8x8 mm scan, (2.9mm scan depth)	AngioPlex 8x8 mm scan, (2.9mm scan depth)	AngioPlex 8x8 mm scan, (2.0mm scan depth)	Identical to the predicate device.
	AngioPlex 12x12 mm scan (2.9mm scan depth)	AngioPlex 12x12 mm scan (2.9mm scan depth	Not Available	Identical to the predicate device.
	AngioPlex HD 6x6 mm scan	AngioPlex HD 6x6 mm scan	Not Available	Identical to the predicate device.
	AngioPlex HD 8x8 mm scan (2.9mm scan depth)	AngioPlex HD 8x8 mm scan (2.9mm scan depth)	Not Available	Identical to the predicate device.
	6 x 6 mm Montage AngioPlex	6 x 6 mm Montage AngioPlex	Not Available	Identical to the predicate device.
	8 x 8 mm Montage AngioPlex	8 x 8 mm Montage AngioPlex	Not Available	Identical to the predicate device.

Retina Tracking	FastTrac Retinal Tracking Track-to-prior to Scan Acquisition tracking.	FastTrac Retinal Tracking Track-to-prior to Scan Acquisition tracking.	FastTrac Retinal Tracking Track-to-prior to Scan Acquisition tracking.	Identical
OCT Angiography Algorithms (OCTA)	- *En face* Algorithm - Segmentation Algorithm - Z-Motion Correction Algorithm - Flow Contrast Algorithm (intensity based + phase= complex-based OCT Angiography)	- *En face* Algorithm - Segmentation Algorithm - Z-Motion Correction Algorithm - Flow Contrast Algorithm (intensity based + phase= complex-based OCT Angiography)	- *En face Algorithm* - Segmentation Algorithm - Z-Motion Correction Algorithm - Flow Contrast Algorithm (intensity based + phase= complex-based OCT Angiography)	Identical
	ANALYSIS AND REPORTS			
RNFL, Macula, Anterior Segment	**Analyses for the Optic Disc:** • ONH/RNFL OU Analysis • Guided Progression Analysis • Advanced Visualization • *En face* • 3D Visualization • Panomap	**Analyses for the Optic Disc:** • ONH/RNFL OU Analysis • Guided Progression Analysis • Advanced Visualization • *En face* • 3D Visualization • Panomap	**Analyses for the Optic Disc:** • ONH/RNFL OU Analysis • Guided Progression Analysis • Advanced Visualization • *En face* • 3D Visualization	Identical

	• Single Eye Summary **Analyses for the Macula:** • Macular thickness • Macular change • Advanced RPE • PanoMap • Advanced visualization • High-definition image • *En face* Analysis • 3D Visualization • Ganglion Cell Guided Progression **Analyses for the Anterior Segment:** • Anterior Segment Analysis • High-Definition Image Analysis • Anterior Chamber Scan Analysis • HD Angle Analysis • HD Cornea Analysis	• Single Eye Summary **Analyses for the Macula:** • Macular thickness • Macular change • Advanced RPE • PanoMap • Advanced visualization • High-definition image • *En face* Analysis • 3D Visualization • Ganglion Cell Guided Progression **Analyses for the Anterior Segment:** • Anterior Segment Analysis • High-Definition Image Analysis • Anterior Chamber Scan Analysis • HD Angle Analysis • HD Cornea Analysis	• Panomap • Single Eye Summary **Analyses for the Macula:** • Macular thickness • Macular change • Advanced RPE • PanoMap • Advanced visualization • High-definition image • *En face Analysis* • 3D Visualization • Ganglion Cell Guided Progression **Analyses for the Anterior Segment:** • Anterior Segment Analysis • High-Definition Image Analysis	

	• Pachymetry Analysis with Epithelial Thickness • Wide Angle-to-Angle Analysis • 3D visualization	• Pachymetry Analysis with Epithelial Thickness • Wide Angle-to-Angle Analysis • 3D visualization	• Anterior Chamber Scan Analysis • HD Angle Analysis • HD Cornea Analysis • Pachymetry Analysis with Epithelial Thickness • Wide Angle-to-Angle Analysis • 3D visualization	
RNFL Thickness Analysis	• OCT Fundus image with RNFL Calculation circle • OCT Image Extracted from Calculation Circle with RNFL Segmentation • RNFL Thickness Map • *Deviation from Normal Map* • Average Thickness	• OCT Fundus image with RNFL Calculation circle • OCT Image Extracted from Calculation Circle with RNFL Segmentation • RNFL Thickness Map • Average Thickness • Quadrant Thicknesses • Clock Hour Thicknesses	• OCT Fundus image with RNFL Calculation circle • OCT Image Extracted from Calculation Circle with RNFL Segmentation • RNFL Thickness Map • *Deviation from Normal Map*	Identical to the reference device.

	• Quadrant Thicknesses • Clock Hour Thicknesses • Symmetry value • TSNIT (or NSTIN format) RNFL thickness graph *with color coding as shown in the Reference Database*	• Symmetry value • TSNIT(or NSTIN format) RNFL thickness graph.	• Average Thickness • Quadrant Thicknesses • Clock Hour Thicknesses • Symmetry value • Normative database TSNIT RNFL thickness graph with color coding	
Optic Nerve Head (ONH) analysis	- Rim Area / Disc Area - Average C/D Ratio - Vertical C/D Ratio: - Cup Volume - Neuro-retinal Rim Thickness - B-scan cross section of the ONH - Automatic outline of disc margin - Automatic outline of cup edge - ONH B-scan slices and segmentation - Reference ONH database color coding	- Rim Area / Disc Area - Average C/D Ratio - Vertical C/D Ratio: - Cup Volume - Neuro-retinal Rim Thickness - B-scan cross section of the ONH - Automatic outline of disc margin - Automatic outline of cup edge - ONH B-scan slices and segmentation - Disc size	- Rim Area / Disc Area - Average C/D Ratio - Vertical C/D Ratio: - Cup Volume - Neuro-retinal Rim Thickness - B-scan cross section of the ONH - Automatic outline of disc margin - Automatic outline of cup edge - ONH B-scan slices and segmentation - Normative ONH database color coding	Identical to the reference device.

	- Disc size		- Disc size	
Guided Progression Analysis (GPA) for RNFL	- Multiple RNFL Thickness Maps - OCT Fundus image with Calculation circle - Overall Average RNFL Thickness Graph - Superior RNFL Thickness Graph - Inferior RNFL Thickness Graph - RNFL Thickness Profile - RNFL Summary: - RNFL Thickness Map Progression - RNFL Thickness Profiles Progression - Average RNFL Thickness Progression Manual selection option of scans to include in change analysis	- Multiple RNFL Thickness Maps - OCT Fundus image with Calculation circle - Overall Average RNFL Thickness Graph - Superior RNFL Thickness Graph - Inferior RNFL Thickness Graph - RNFL Thickness Profile - RNFL Summary: - RNFL Thickness Map Progression - RNFL Thickness Profiles Progression - Average RNFL Thickness Progression Manual selection option of scans to include in change analysis	- Multiple RNFL Thickness Maps - Multiple Deviation from Normal Maps - OCT Fundus image with Calculation circle - Overall Average RNFL Thickness Graph - Superior RNFL Thickness Graph - Inferior RNFL Thickness Graph - RNFL Thickness Profile - RNFL Summary: - RNFL Thickness Map Progression - RNFL Thickness Profiles Progression - Average RNFL Thickness Progression - Manual selection option of scans to include in change analysis	Identical to the predicate device.

Guided Progression Analysis (GPA) for Ganglion Cell/IPL	- Sequential display of Macular images in Guided Progression Analysis (GPA) for Ganglion Cell Layer/Inner Plexiform Layer (GCL/IPL) - Multiple GCL/IPL Thickness Maps - Overall Average GCL/IPL Thickness Graph - Superior GCL/IPL Thickness Graph - Inferior GCL/IPL Thickness Graph - GCL/IPL Summary: - GCL Thickness Map Progression - GCL Thickness Progression	- Sequential display of Macular images in Guided Progression Analysis (GPA) for Ganglion Cell Layer/Inner Plexiform Layer (GCL/IPL) - Multiple GCL/IPL Thickness Maps - Overall Average GCL/IPL Thickness Graph - Superior GCL/IPL Thickness Graph - Inferior GCL/IPL Thickness Graph - GCL/IPL Summary: - GCL Thickness Map Progression - GCL Thickness Progression	- Sequential display of Macular images in Guided Progression Analysis (GPA) for Ganglion Cell Layer/Inner Plexiform Layer (GCL/IPL) - Multiple GCL/IPL Thickness Maps - Overall Average GCL/IPL Thickness Graph - Superior GCL/IPL Thickness Graph - Inferior GCL/IPL Thickness Graph - GCL/IPL Summary: - GCL Thickness Map Progression - GCL Thickness Progression	Identical
Macular Thickness Analysis and Display	- Fundus Image with scan cube overlay - Average thickness and volume table - ETDRS grid map with reference database color coding - Slice navigators	- Fundus Image with scan cube overlay - Average thickness and volume table - ETDRS grid map - Slice navigators - Horizontal B-scan (X-image)	- Fundus Image with scan cube overlay - Average thickness and volume table - ETDRS grid map with normative database color coding - Slice navigators	Identical to the reference device

	- Horizontal B-scan (X-image) - Vertical slice - A-scan (Y-image) - 3-D color ILM-RPE thickness map - 3-D surface map of ILM - 3-D surface map of RPE - Segmentation line toggle - Measurement calipers - Automatic fovea finding and coordinates - Assorted controls for aligning ETDRS grid - High-Resolution Images option - Edit Layers (enhanced interface) - Zoom controls - Save Image options - Movie option	- Vertical slice - A-scan (Y-image) - 3-D color ILM-RPE thickness map - 3-D surface map of ILM - 3-D surface map of RPE - Segmentation line toggle - Measurement calipers - Automatic fovea finding and coordinates - Assorted controls for aligning ETDRS grid - High-Resolution Images option - Edit Layers (enhanced interface) - Zoom controls - Save Image options - Movie option	- Horizontal B-scan (X-image) - Vertical slice - A-scan (Y-image) - 3-D color ILM-RPE thickness map - 3-D surface map of ILM - 3-D surface map of RPE - Segmentation line toggle - Measurement calipers - Automatic fovea finding and coordinates - Assorted controls for aligning ETDRS grid - High-Resolution Images option - Edit Layers (enhanced interface) - Zoom controls - Save Image options - Movie option	

High Definition Display	- Fundus image with OCT b-scan reference line (slice navigator) overlays - Enlarged B-scan image of selected line - Up to 5 thumbnail images	- Fundus image with OCT b-scan reference line (slice navigator) overlays - Enlarged B-scan image of selected line - Up to 5 thumbnail images	- Fundus image with OCT b-scan reference line (slice navigator) overlays - Enlarged B-scan image of selected line - Up to 5 thumbnail images	Identical
Ganglion Cell OU Analysis	- GCA Thickness Map - GCA Deviation Map - Six sectors of average thickness – color coded per RDB limits - Horizontal Macular B-scan - Vertical Macular B-scan - Average GCL+IPL thickness (chart) - Data available on screen & on printout	- GCA Thickness Map - Six sectors of average thickness - Horizontal Macular B-scan - Vertical Macular B-scan - Average GCL+IPL thickness (chart) - Minimum GCL+IPL thickness (chart) - Data available on screen & on printout	- GCA Thickness Map - GCA Deviation Map - Six sectors of average thickness – color coded per NDB limits - Horizontal Macular B-scan - Vertical Macular B-scan - Average GCL+IPL thickness (chart) - Minimum GCL+IPL thickness (chart) - Data available on screen & on printout	Identical to the reference device

Single Eye Summary (Data from macula scan and optic disc scan are shown in one report)	**Macula Analysis:** - en face image of macular cube - Macular Thickness map - ETDRS grid sector thicknesses with comparison to reference data - Macular B-scan **ONH/RNFL Analysis:** - en face image of Optic Disc Cube - RNFL Thickness map - Data Table with RNFL and ONH data - RNFL TSNIT Thickness graph - ONH B-scan - Data available on screen & on printout	**Macula Analysis:** - en face image of macular cube - Macular Thickness map - ETDRS grid sector thicknesses - Macular B-scan **ONH/RNFL Analysis:** - en face image of Optic Disc Cube - RNFL Thickness map - Data Table with RNFL and ONH data - RNFL TSNIT Thickness graph - ONH B-scan - Data available on screen & on printout	**Macula Analysis:** - en face image of macular cube - Macular Thickness map - ETDRS grid sector thicknesses with comparison to normative data - Macular B-scan **ONH/RNFL Analysis:** - en face image of Optic Disc Cube - RNFL Thickness map - Data Table with RNFL and ONH data - RNFL TSNIT Thickness graph - ONH B-scan - Data available on screen & on printout	Identical to the reference device
Advanced RPE Analysis	- Advanced RPE Analysis	- Advanced RPE Analysis	- Advanced RPE Analysis	Identical
PanoMap Analysis	- Macular Cube 512x128 or - Macular Cube 200x200 and - Optic Disc Cube 200x200 scan for the same eye.	- Macular Cube 512x128 or - Macular Cube 200x200 and - Optic Disc Cube 200x200 scan for the same eye. - Montage of Macular Cube	- Macular Cube 512x128 or - Macular Cube 200x200 and - Optic Disc Cube	Identical

	- Montage of Macular Cube and Optic Disc Cube OCT en face images	and Optic Disc Cube OCT en face images	200x200 scan for the same eye. - Montage of Macular Cube and Optic Disc Cube OCT en face images	
Wellness Exam Report	This is an OU wide field analysis that combines information from the macular thickness analysis. PanoMap analysis, RNFL and ONH analysis and ganglion cell OU analysis into one report.	- This is an OU wide field analysis that combines information from the macular thickness analysis. PanoMap analysis, RNFL and ONH analysis and ganglion cell OU analysis into one report.	- Not Available	Identical to the predicate device.
OCT Angiography Report / Analysis	- OCT Angiography Report - OCT Angiography Change Analysis	- OCT Angiography Report - OCT Angiography Change Analysis	- OCT Angiography Report - OCT Angiography Change Analysis	Identical
ORCC & RPE-to-RPE Fit Slabs (pre-set) in OCTA Analysis	- ORCC (Outer Retina to ChorioCapillaris), Sub-RPE, RPE-to-RPEFit slabs in OCTA Analysis	- ORCC (Outer Retina to ChorioCapillaris), Sub-RPE, RPE-to-RPEFit slabs in OCTA Analysis	Not Available	Identical to the predicate device.

Anterior Segment - Analysis with Quantitative Measurement Tools	**Anterior 5-Line Raster** - Thickness calipers **Anterior Segment Cube** - 3D Visualization - Thickness calipers **Pachymetry Scan** - Corneal thickness - Epithelial thickness	**Anterior 5-Line Raster** - Thickness calipers **Anterior Segment Cube** - 3D Visualization - Thickness calipers **Pachymetry Scan** - Corneal thickness - Epithelial thickness	**Anterior 5-Line Raster** - Thickness calipers **Anterior Segment Cube** - 3D Visualization - Thickness calipers **Pachymetry Scan** - Corneal thickness Epithelial thickness	Identical
ONH Angiography Two-Visit Comparison	- visual side by side comparison of two angiography visits on the analysis screen and corresponding report print out.	- visual side by side comparison of two angiography visits on the analysis screen and corresponding report print out.	visual side by side comparison of two angiography visits on the analysis screen and corresponding report print out.	Identical
Reference Database, Diverse	- *Retinal Nerve Fiber Layer (RNFL) Thickness* - *Macular Thickness* - *Optic Nerve Head (ONH) Parameters* - *Ganglion Cell/IPL Thickness*	Not Applicable	- Retinal Nerve Fiber Layer (RNFL) Thickness - Macular Thickness - Optic Nerve Head (ONH) Parameters - Ganglion Cell/IPL Thickness	Equivalent to the reference device. CIRRUS 6000 RDB provides additional colors when the measurements are within overlapping confidence intervals of the quantile limits.
	FUNDUS IMAGING			
Methodology	Line Scanning Ophthalmoscope	Line Scanning Ophthalmoscope	Line Scanning Ophthalmoscope	Identical

Optical Source	Super Luminescent Diode (SLD) 750 nm	Super Luminescent Diode (SLD) 750 nm	Super Luminescent Diode (SLD) 750 nm	Identical
Optical Power	< 1.5 mW at the cornea	< 1.5 mW at the cornea	< 1.5 mW at the cornea	Identical
Field of View	36 degrees W x 30 degrees H	36 degrees W x 30 degrees H	36 degrees W x 30 degrees H	Identical
Frame Rate	> 20 Hz	> 20 Hz	> 20 Hz	Identical
Transverse Resolution	25 µm (in tissue)	25 µm (in tissue)	25 µm (in tissue)	Identical
	IRIS IMAGING			
Methodology	CMOS camera and LED illumination	CMOS camera and LED illumination	CMOS camera and LED illumination	Identical
Optical source	1280 x 1024	1280 x 1024	1280 x 1024	Identical
Resolution	During alignment	During alignment	During alignment	Identical
Live iris image	Light emitting diode (LED), 700 nm	Light emitting diode (LED), 700 nm	Light emitting diode (LED), 700 nm	Identical
	FIXATION			
Internal fixation source	LED Array, 21 positions	LED Array, 21 positions	LED Array, 9 positions	Identical to the predicate device.
Internal fixation focus adjustment	-20D to +20D (diopters)	-20D to +20D (diopters)	-20D to +20D (diopters)	Identical
External fixation source	Mechanically adjustable arm with LED at the tip	Mechanically adjustable arm with LED at the tip	Mechanically adjustable arm with LED at the tip	Identical
	ELECTRICAL, PHYSICAL, ENVIRONMENTAL			
Configuration	Patient module, computer, media and power supply integrated into single compact module	Patient module, computer, media and power supply integrated into single compact module	Patient module, computer, media and power supply integrated into single compact module	Identical
Computer	High performance multi-core processor CORE i7 @ 3.6 GHz, 32GB RAM, 2TB Hard Disk, Windows 10, SSD	High performance multi-core processor CORE i7 @ 3.6 GHz, 32GB RAM, 2TB Hard Disk, Windows 10, SSD	High performance multi-core processor CORE i7 @ 3.1GHz, 16GB RAM, 2TB Hard Disk, Windows 10	Identical to the predicate device.

Input Devices	Computer mouse/keyboard	Computer mouse/keyboard	Computer mouse/keyboard	Identical
Display	22” Widescreen HD (Resolution 1920 x 1080)	22” Widescreen HD (Resolution 1920 x 1080)	19” Color Flat Panel Display (Resolution 1280 x 1024)	Identical to the predicate device.
Network	Network and additional USB connectors under rear cover.	Network and additional USB connectors under rear cover.	Network and additional USB connectors under rear cover.	Identical
Optical media formats supported	6 USB Media ports	6 USB Media ports	6 USB Media ports	Identical
Weight	35 kg (77 lbs) (without monitor)	35 kg (77 lbs) (without monitor)	36 kg (80 lbs)	Identical to the predicate device
Dimensions	62.2L x 42.5W x 49.4H (cm)	62.2L x 42.5W x 49.4H (cm)	62.2L x 42.5W x 49.4H (cm)	Identical
Electrical rating (115V)	100-120 V~ 50-60 Hz 6.3A	100-120 V~ 50-60 Hz 6.3A	100-120 V~ 50-60 Hz 6.3A	Identical
Power rating (115V)	500W	500W	350W	Identical to the predicate device
Fuse rating (115V)	T 6.3 A 250V	T 6.3 A 250V	T 5A 250V	Identical to the predicate device
Max amperage and voltage rating	T 6.3A 250V	T 6.3 A 250V	T 5A 250V	Identical to the predicate device
Environmental Conditions: Transport and Storage	Temp. -40° to +70° C 30% to 75% (excluding condensation) Atmospheric Pressure 500 to 1060 hPa	Temp. -40° to +70° C 30% to 75% (excluding condensation) Atmospheric Pressure 500 to 1060 hPa	Temp. -40° to +70° C 30% to 75% (excluding condensation) Atmospheric Pressure 500 to 1060 hPa	Identical
Environmental Conditions: Operation	Temperature: +10 to +35° C Relative Humidity: 30% to 75% (excluding condensation) Atmospheric Pressure: 700 to 1060 hPa	Temperature: +10 to +35° C Relative Humidity: 30% to 75% (excluding condensation) Atmospheric Pressure: 700 to 1060 hPa	Temperature: +10 to +35° C Relative Humidity: 30% to 75% (excluding condensation) Atmospheric Pressure: 700 to 1060 hPa	Identical

Enclosure-Flammability Ratings	UL 94V-0	UL 94V-0	UL 94V-0	Identical
	UX			
Protocol buttons	- Workflow buttons filter scan patterns for acquisition	- Workflow buttons filter scan patterns for acquisition	Not Available	Identical to the predicate device
Scan Protocols	- user-selectable scan protocols on the patient management screen that define a specific set of scans to be acquired.	- User-selectable scan protocols on the patient management screen that define a specific set of scans to be acquired.	Not Available	Identical to the predicate device
Preferred Analysis	- allows the user to preconfigure the preferred analysis to auto load. This is a UI update that allows the user to see first 4 preferred analyses every time	- Allows the user to preconfigure the preferred analysis to auto load. This is a UI update that allows the user to see first 4 preferred analyses every time	Not Available	Identical to the predicate device
Anterior Segment Caliper Tool	- This tool is able to snap to the surfaces identified by the software, including anterior cornea and posterior cornea.	This tool is able to snap to the surfaces identified by the software, including anterior cornea and posterior cornea.	Not Available	Identical to the predicate device
Analysis switch eye	- allows the user to switch to the 'other' eye for the same analyses	allows the user to switch to the 'other' eye for the same analyses	Not Available	Identical to the predicate device
New Circle Tool for Angiography	- a manually placed circle tool for annotation purposes	a manually placed circle tool for annotation purposes	Not Available	Identical to the predicate device

New Freehand Tool for Angiography	- A scalable circle and freeform measurement tools for the OCT Angiography and ONH Angiography enface image which displays estimated values for area and perimeter/diameter	A scalable circle and freeform measurement tools for the OCT Angiography and ONH Angiography enface image which displays estimated values for area and perimeter/diameter	Not Available	Identical to the predicate device

7. SUMMARY OF STUDIES

Non-Clinical Performance Testing

Non-clinical system testing was provided on the predicate K222200 and no new non-clinical information is provided in this submission since sterility, shelf-life, biocompatibility, and animal testing was not performed as there were no modifications made to the device in this regard.

Other verification and validation testing (such as software) was conducted, and documentation was provided as recommended by the FDA's Guidance for Industry and Staff "Content of Premarket Submissions for Device Software Functions (June 2023)". All testing passed.

Clinical Performance Testing

Repeatability and Reproducibility testing was leveraged from the K222200; and thus, was not provided in this submission.

The addition of the reference database required new testing which is summarized below.

A prospective, multi-site reference database (RDB) study was conducted at eight (8) clinical sites across the USA to develop the CIRRUS 6000 RDB for macular thickness and optic nerve head scan values.

The Subject Device's RDB was created to help clinicians assess and effectively compare a patient's measurements to that of healthy subjects, representative of the general population.

The eligibility criteria included subjects 18 years of age and older, best corrected visual acuity (BCVA) of 20/40 or better in either eye, IOP < 21 mmHg in either eye, manifest refraction spherical equivalent (MRSE) within -8 to +3D range and astigmatism correction < -2D in the study eye.

Subjects were excluded if there was presence of any clinically significant vitreal, retinal optic nerve, or choroidal disease in the study eye, including glaucoma or suspected glaucoma. This was assessed based on clinical examination and fundus photography.

History of ocular surgery (except for uncomplicated cataract surgery and/or refractive surgery), history of unreliable or visual field abnormalities, dense media opacities, active infection, current ocular medication, or hydroxychloroquine/chloroquine use were also exclusion criteria.

Subjects with diabetes, leukemia, AIDS, dementia, multiple sclerosis, or debilitating disease were excluded from the study. One thousand subjects (1000) were enrolled and screened, and one eye from eight hundred and seventy (870) subjects was included in analysis. Only the scans that met the pre-determined image quality criteria were included in analysis. There were no adverse events or adverse device effects recorded during the study.

Demographic summary, subjects with any valid scans

Factor	Summary
N (subjects)	870
Age (years)	
Mean(SD)	53.6 (15.1)
Median	56.0
Min, Max	[18.0, 88.0]
Age (by sampling categories)	
Age 18-49	247/870 (28.4%)
Age 50-88	623/870 (71.6%)
Age (by decade)	
Age 18-29	87/870 (10.0%)
Age 30-39	83/870 (9.5%)
Age 40-49	77/870 (8.9%)
Age 50-59	275/870 (31.6%)
Age 60-69	237/870 (27.2%)
Age 70 and older	111/870 (12.8%)
Gender n (%)	
Female	511/870 (58.7%)
Male	359/870 (41.3%)
Race n (%)	
Caucasian/White	474/870 (54.5%)
Black/African American	168/870 (19.3%)
Asian	160/870 (18.4%)
American.Ind/AK.Native	4/870 (0.5%)
Hawaiian/Pac.Islander	2/870 (0.2%)
Other	41/870 (4.7%)
Declines to State	21/870 (2.4%)
Ethnicity n (%)	
Not Hispanic or Latino	742/870 (85.3%)
Hispanic or Latino	105/870 (12.1%)
Declines to State	23/870 (2.6%)
Study Eye n (%)	
OD	438/870 (50.3%)
OS	432/870 (49.7%)

Summary of Ophthalmologic Evaluation, subjects with any valid scans

Factor	Summary
N (subjects)	870
MRSE	
Mean(SD)	-0.8 (2.0)
Median	-0.25
Min, Max	[-7.75, 3.0]
Cylinder	
Mean(SD)	-0.6 (0.5)
Median	-0.5
Min, Max	[-2.0, 0.0]
BCVA	
20/15	21/870 (2.4%)
20/20	761/870 (87.5%)
20/25	74/870 (8.5%)
20/30	13/870 (1.5%)
20/40	1/870 (0.1%)
BCVA (logMAR[1])	
Mean(SD)	0.01 (0.04)
Median	0.00
Min, Max	[-0.12, 0.30]
IOP (mmHg)	
Mean(SD)	14.5 (3.1)
Median	14.0
Min, Max	[6.0, 21.0]
Axial Length (mm)	
Mean(SD)	24.1 (1.1)
Median	24.0
Min, Max	[21.2, 28.4]
ONH, Horizontal C/D	
Mean(SD)	0.334 (0.121)
Median	0.300
Min, Max	[0.100, 0.800]
ONH, Vertical C/D	
Mean(SD)	0.336 (0.122)
Median	0.300
Min, Max	[0.100, 0.700]

1-Converted from Snellen score using: logMAR = $\log_{10}$(SNELLEN/20).

Table Qualified scans, by scan type.

	Macular Cube 200x200	Macular Cube 512x128	Optic Disc Cube 200x200
Acceptable Scans	826	831	854

Reference range limits were calculated by regression analysis for the 1st, 5th, 95th, and the 99th percentiles for the OCT structural measurements. The reference limits were calculated using age as a covariate for Macular Thickness and Ganglion Cell Thickness. Both Age and Optic Disc Size were used as covariates for ONH parameters and RNFL thickness. From this study, CIRRUS 6000 reference limits were established for Macular Thickness, Ganglion Cell Thickness, Optic Nerve Head parameters, and Retinal Nerve Fiber Layer thickness values.

8. CONCLUSION

The subject device maintains existing technological characteristics of the predicate device while integrating a new reference database. The following parameters include the application of color-coded indicators that delineate the reference database limits: macular thickness, ganglion cell thickness, ONH values, and RNFL thickness. The technological characteristics and risk profile of the subject device are equivalent to both the predicate device and reference device.

Results of the performance testing support a determination of substantial equivalence between the subject device and the predicate device for the proposed intended use. A reference device was used to support the test methodology used to validate the new reference database. Therefore, the subject and predicate devices are deemed to be substantially equivalent.