Carl Zeiss Meditec Inc
% Tanesha Bland
Senior Regulatory Affairs Specialist
Carl Zeiss Meditec USA Inc
5300 Central Parkway
Dublin, California 94568

Re: K222200
Trade/Device Name: Cirrus HD-OCT
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO
Dated: March 2, 2023
Received: March 6, 2023

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 (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 located 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.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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.

510(k) Number *(if known)*
K222200

Device Name
CIRRUS HD-OCT Model 6000

Indications for Use *(Describe)*
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 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.
This device is Prescription Use (Rx) only.

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 is provided below.

1. SUBMITTER

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Date Prepared: April 12, 2023

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 5000 (K181534)
Classification:	21CFR886.1570 Optical Coherence Tomography (OCT)
Regulatory Class:	II
Product Code:	OBO, IYO, ITX

4. DEVICE DESCRIPTION

The CIRRUS™ HD-OCT Model 6000 is indicated for in-vivo viewing, axial cross-sectional, and three-dimensional imaging and measurement of anterior and posterior ocular structures. The clinical purpose of this device has not been modified as compared to the predicate.

CIRRUS 6000 uses the same optical system, architecture, and principle of operation as the previously cleared CIRRUS 5000 (K181534). CIRRUS 6000 has a 100 kHz scan rate for all structural and angiography scans. The primary impact of the higher acquisition speed is its impact on signal-to-noise ratio. The signal-to-noise ratio in the subject device is calibrated to match the specifications of the predicate device. The CIRRUS 6000 uses the same segmentation algorithms as the predicate device and therefore the segmentation results will be equivalent.

In addition to the acquisition speed change, CIRRUS 6000 also has a wider field of view (FOV) and has increased the number of fixation points to 21.

5. INDICATIONS FOR USE

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 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.

This device is Prescription Use (Rx) only.

6. SUBSTANTIAL EQUIVALENCE TO PRIMARY PREDICATE

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

Device	Subject Device – CIRRUS 6000	Predicate Device – CIRRUS 5000 (K181534)	Equivalency Analysis
Indications for Use	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 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.	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 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.	Identical (except the normative database)

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

Device	CIRRUS™ HD-OCT 6000 v. 11.5.4 Subject Device	CIRRUS™ HD-OCT 5000 v. 10.0 Predicate Device (K181534)	Analysis
Device Classification Name	Tomography, Optical Coherence	Tomography, Optical Coherence	Identical
Generic/ Common Name	Optical Coherence Tomography (OCT)	Optical Coherence Tomography (OCT)	Identical
Classification Product Code	OBO	OBO	Identical
Class	II	II	Identical
Technology	Spectral Domain (Spatially encoded Frequency Domain and Fourier Domain Principle) OCT	Spectral Domain (Spatially encoded Frequency Domain and Fourier Domain Principle) OCT	Identical
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	Identical
Models	6000	5000	N/A
OCT IMAGING			
Methodology	Spectral domain OCT (SD-OCT)	Spectral domain OCT (SD-OCT)	Identical

Device	CIRRUS™ HD-OCT 6000 v. 11.5.4 Subject Device	CIRRUS™ HD-OCT 5000 v. 10.0 Predicate Device (K181534)	Analysis
OCT Optical Source	OCT Super Luminescent Diode, 840 nm wavelength	OCT Super Luminescent Diode, 840 nm wavelength	Identical
Optical Power	1200 µW +/- 300 µW (0.9 - 1.5 mW) at the cornea	< 775 µW at the cornea	Different
Scan Speed	100,000 A-scans per second	27,000 A-scans per second *68,000 A-scans per second only for OCT Angiography*	Different
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	2.0 mm	Different
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.	Identical
Axial Scan Depth (Max) –Anterior Segment	2.0 mm (Anterior 5-Line Raster) – 1024 points2.0 mm (Anterior Segment Cube) – 1024 points	2.0 mm (Anterior 5-Line Raster) – 1024 points2.0 mm (Anterior Segment Cube) – 1024 points	Identical

Device	CIRRUS™ HD-OCT 6000 v. 11.5.4 Subject Device	CIRRUS™ HD-OCT 5000 v. 10.0 Predicate Device (K181534)	Analysis
	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	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	
External Anterior Segment 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) 31° x 31° on retina (Maximum)	Different
Transverse Scan Range –Anterior Segment	3 mm (Minimum) 15 mm (Maximum)	3 mm (Minimum) 15 mm (Maximum)	Identical
Axial Resolution	5 µm (in tissue)	5 µm (in tissue)	Identical
Transverse Resolution – Retina	≤ 15 µm (in tissue)	≤ 15 µm (in tissue)	Identical

Device	CIRRUS™ HD-OCT 6000 v. 11.5.4 Subject Device	CIRRUS™ HD-OCT 5000 v. 10.0 Predicate Device (K181534)	Analysis
Transverse Resolution – Anterior Segment	20 µm (in tissue) 20 µm @ 6mm FOV 25 µm @ 9mm FOV 45 µm @ 15mm FOV	20 µm (in tissue) 20 µm @ 6mm FOV 25 µm @ 9mm FOV 45 µm @ 15mm FOV	Identical
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.	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	Identical
	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	Identical
	Not Available	5-Line Raster	Different, scan type not available for CIRRUS 6000
	HD (high-definition) Raster - HD 1 Line 100x (2.9 mm depth and up to 12 mm in length)	HD (high-definition) Raster - HD 1 Line 100x (2.0 mm depth and up to 9 mm in length)	Identical except for HD 1 Line 100x scan depth and max length

Device	CIRRUS™ HD-OCT 6000 v. 11.5.4 Subject Device	CIRRUS™ HD-OCT 5000 v. 10.0 Predicate Device (K181534)	Analysis
	- HD 21 Line - HD Radial - HD Cross - HD 5-Line Raster	- HD 21 Line - HD Radial - HD Cross - HD 5-Line Raster	
	Anterior Segment Cube 512 x 128	Anterior Segment Cube 512 x 128	Identical
	Anterior Segment 5-Line Raster	Anterior Segment 5-Line Raster	Identical
	HD Angle	HD Angle	Identical
	Anterior Chamber	Anterior Chamber	Identical
	Wide Angle-to-Angle	Wide Angle-to-Angle	Identical
	HD Cornea	HD Cornea	Identical
	Pachymetry	Pachymetry	Identical
OCT Angiography scans	**Scans:**	**Scans:**	**Scans:**
	AngioPlex 3x3 mm scan	AngioPlex 3x3 mm scan	Identical
	AngioPlex 6x6 mm scan	AngioPlex 6x6 mm scan	Identical

Device	CIRRUS™ HD-OCT 6000 v. 11.5.4 Subject Device	CIRRUS™ HD-OCT 5000 v. 10.0 Predicate Device (K181534)	Analysis
	AngioPlex 8x8 mm scan, (2.9mm scan depth)	AngioPlex 8x8 mm scan, (2.0mm scan depth)	Different
	AngioPlex 12x12 mm scan (2.9mm scan depth)	Not Available	Different
	AngioPlex HD 6x6 mm scan	Not Available	Different
	AngioPlex HD 8x8 mm scan (2.9mm scan depth)	Not Available	Different
	6 x 6 mm Montage AngioPlex	Not Available	Different
	8 x 8 mm Montage AngioPlex	Not Available	Different
Retina 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)	Identical
ANALYSIS AND REPORTS			

Device	CIRRUS™ HD-OCT 6000 v. 11.5.4 Subject Device	CIRRUS™ HD-OCT 5000 v. 10.0 Predicate Device (K181534)	Analysis
RNFL, Macula, Anterior Segment	**Analyses for the Optic Disc:** • ONH/RNFL OU Analysis • Guided Progression Analysis • Advanced Visualization • *En face* • 3D Visualization • 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	**Analyses for the Optic Disc:** • ONH/RNFL OU Analysis • Guided Progression Analysis • Advanced Visualization • *En face* • 3D Visualization • 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	Identical

Device	CIRRUS™ HD-OCT 6000 v. 11.5.4 Subject Device	CIRRUS™ HD-OCT 5000 v. 10.0 Predicate Device (K181534)	Analysis
	• 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 • Pachymetry Analysis with Epithelial Thickness • Wide Angle-to-Angle 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 • 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	• OCT Fundus image with RNFL Calculation circle • OCT Image Extracted from Calculation Circle with RNFL Segmentation	Identical, except the normative database. CIRRUS 6000 adds NSTIN display orientation to RNFL thickness chart and removed normative database.

Device	CIRRUS™ HD-OCT 6000 v. 11.5.4 Subject Device	CIRRUS™ HD-OCT 5000 v. 10.0 Predicate Device (K181534)	Analysis
	• RNFL Thickness Map • Average Thickness • Quadrant Thicknesses • Clock Hour Thicknesses • Symmetry value • TSNIT (or NSTIN format) RNFL thickness graph	• RNFL Thickness Map • Deviation from Normal Map • 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	• 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	Identical, except the normative database. Normative ONH database color coding functionality removed.

Device	CIRRUS™ HD-OCT 6000 v. 11.5.4 Subject Device	CIRRUS™ HD-OCT 5000 v. 10.0 Predicate Device (K181534)	Analysis
	• Automatic outline of cup edge • ONH B-scan slices and segmentation • Disc size	• Automatic outline of cup edge • ONH B-scan slices and segmentation • Normative ONH database color coding • Disc size	

Device	CIRRUS™ HD-OCT 6000 v. 11.5.4 Subject Device	CIRRUS™ HD-OCT 5000 v. 10.0 Predicate Device (K181534)	Analysis
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: o RNFL Thickness Map Progression o RNFL Thickness Profiles Progression o 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: o RNFL Thickness Map Progression o RNFL Thickness Profiles Progression o Average RNFL Thickness Progression Manual selection option of scans to include in change analysis	Identical, except the normative database. Multiple deviation from Normal maps removed.

Device	CIRRUS™ HD-OCT 6000 v. 11.5.4 Subject Device	CIRRUS™ HD-OCT 5000 v. 10.0 Predicate Device (K181534)	Analysis

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
			Identical

Macular Thickness Analysis and Display	- 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, except the normative database. Normative database removed from ETDRS grid map with color coding.

Device	CIRRUS™ HD-OCT 6000 v. 11.5.4 Subject Device	CIRRUS™ HD-OCT 5000 v. 10.0 Predicate Device (K181534)	Analysis
	- 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	

Device	CIRRUS™ HD-OCT 6000 v. 11.5.4 Subject Device	CIRRUS™ HD-OCT 5000 v. 10.0 Predicate Device (K181534)	Analysis
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	Identical
Ganglion Cell OU Analysis	- 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, except the normative database. Removed color coded NDB limits for Six sectors of average thickness.

Device	CIRRUS™ HD-OCT 6000 v. 11.5.4 Subject Device	CIRRUS™ HD-OCT 5000 v. 10.0 Predicate Device (K181534)	Analysis
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 - 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, except the normative database. Removed color coded NDB for ETDRS grid sector thickness.
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. - Montage of Macular Cube and Optic Disc Cube OCT en face images	- Macular Cube 512x128 or - Macular Cube 200x200 and - Optic Disc Cube 200x200 scan for the same eye. - Montage of Macular Cube and Optic Disc Cube OCT en face images	Identical

Device	CIRRUS™ HD-OCT 6000 v. 11.5.4 Subject Device	CIRRUS™ HD-OCT 5000 v. 10.0 Predicate Device (K181534)	Analysis
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.	- Not Available	Different
OCT Angiography Report / 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	- Not Available	Different, these slabs are calculated from existing slabs on the predicate. Sub-RPE in CIRRUS 6000 v11.5.4 was formerly called Choriocapillaris in CIRRUS 5000 v10.0

Device	CIRRUS™ HD-OCT 6000 v. 11.5.4 Subject Device	CIRRUS™ HD-OCT 5000 v. 10.0 Predicate Device (K181534)	Analysis
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	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.	Identical
Normative Database, Diverse	- Not Available	- Retinal Nerve Fiber Layer (RNFL) Thickness - Macular Thickness - Optic Nerve Head (ONH) Parameters - Ganglion Cell/IPL Thickness	Different, CIRRUS 6000 does not include normative reference database functionality for scans acquired from the CIRRUS 6000.
FUNDUS IMAGING			
Methodology	Line Scanning Ophthalmoscope	Line Scanning Ophthalmoscope	Identical
Optical Source	Super Luminescent Diode (SLD)	Super Luminescent Diode (SLD)	Identical

Device	CIRRUS™ HD-OCT 6000 v. 11.5.4 Subject Device	CIRRUS™ HD-OCT 5000 v. 10.0 Predicate Device (K181534)	Analysis
	750 nm	750 nm	
Optical Power	< 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	Identical
Frame Rate	> 20 Hz	> 20 Hz	Identical
Transverse Resolution	25 µm (in tissue)	25 µm (in tissue)	Identical
IRIS IMAGING			
Methodology	CMOS camera and LED illumination	CMOS camera and LED illumination	Identical
Optical source	1280 x 1024	1280 x 1024	Identical
Resolution	During alignment	During alignment	Identical
Live iris image	Light emitting diode (LED), 700 nm	Light emitting diode (LED), 700 nm	Identical
FIXATION			
Internal fixation source	LED Array, 21 positions (Same 9 positions as CIRRUS 5000 plus an additional 12 positions)	LED Array, 9 positions	Different
Internal fixation focus adjustment	-20D to +20D (diopters)	-20D to +20D (diopters)	Identical

Device	CIRRUS™ HD-OCT 6000 v. 11.5.4 Subject Device	CIRRUS™ HD-OCT 5000 v. 10.0 Predicate Device (K181534)	Analysis
External fixation source	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	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 @ 3.1GHz, 16GB RAM, 2TB Hard Disk, Windows 10	Different
Input Devices	Computer mouse/keyboard	Computer mouse/keyboard	Identical
Display	22" Widescreen HD (Resolution 1920 x 1080)	19" Color Flat Panel Display (Resolution 1280 x 1024)	Different
Network	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	Identical
Weight	35 kg (77 lbs) (without monitor)	36 kg (80 lbs)	Different
Dimensions	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	Identical
Power rating (115V)	500W	350W	Different

Device	CIRRUS™ HD-OCT 6000 v. 11.5.4 Subject Device	CIRRUS™ HD-OCT 5000 v. 10.0 Predicate Device (K181534)	Analysis
Fuse rating (115V)	T 6.3 A 250V	T 5A 250V	Different, power consumption for enhanced speed and capabilities push the power budget to the place where higher rated power supply is needed
Max amperage and voltage rating	T 6.3A 250V	T 5A 250V	Different, Compliant with IEC 60601 requirements.
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	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	Identical
Enclosure-Flammability Ratings	UL 94V-0	UL 94V-0	Identical
UX			

Device	CIRRUS™ HD-OCT 6000 v. 11.5.4 Subject Device	CIRRUS™ HD-OCT 5000 v. 10.0 Predicate Device (K181534)	Analysis
Protocol buttons	- Workflow buttons filter scan patterns for acquisition	Not Available	Different
Scan Protocols	- user-selectable scan protocols on the patient management screen that define a specific set of scans to be acquired.	Not Available	Different
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	Not Available	Different This is a workflow improvement, not a technical improvement. This provides the user a streamlined selection based on their preferences and/or practices.
Anterior Segment Caliper Tool	- This tool is able to snap to the surfaces identified by the software, including anterior cornea and posterior cornea.	Not Available	Different User interface improvements
Analysis switch eye	- allows the user to switch to the 'other' eye for the same analyses	Not Available	Different, user interface improvements
New Circle Tool for Angiography	- a manually placed circle tool for annotation purposes	Not Available	Different, user interface improvements

Device	CIRRUS™ HD-OCT 6000 v. 11.5.4 Subject Device	CIRRUS™ HD-OCT 5000 v. 10.0 Predicate Device (K181534)	Analysis
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	Not Available	Different, user interface improvements

7. SUMMARY OF STUDIES

Non-Clinical Performance Testing

Non-clinical system testing provided an evaluation of the performance of the system relevant to each of the system specifications. The functional and system level testing showed that the system met the defined specifications. ZEISS demonstrated non-clinical equivalency between the CIRRUS 6000 and CIRRUS 5000 scan data using a phantom retina, which shows the equivalency of the segmentation results as the segmentation algorithms are the same in both instruments.

Sterility, Shelf-Life, Biocompatibility, and Animal testing was not required for this submission and thus not used in substantiation of equivalence.

Software verification and validation testing were conducted, and documentation was provided as recommended by the FDA's Guidance for Industry and Staff "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". There have been no changes in level of concern or software architecture. All testing passed.

Due to changes to hardware stated in the device description section, updated IEC 60601-1 and IEC 60601-1-2 was provided to demonstrate that the changes did not have a negative impact on the device's electrical safety profile. All testing has passed.

Bench Testing followed FDA's 510(k) OCT Pilot Program Recommendations

- Spatial performance
- Device sensitivity
- OCT angiography
- Auxiliary functions testing
- Safety and Essential Performance: IEC 60601-1
- Electromagnetic Compatibility: IEC 60601-1-2
- Usability: IEC 62366-1
- Optical resolution testing (lateral and axial resolution)
- Light Hazard Protection for Ophthalmic Instruments: ANSI Z80.36-2016
- Gage R&R segmentation comparison between CIRRUS 5000 and CIRRUS 6000

All the above testing passed. No additional safety or performance concerns have been raised during development or device testing.

Clinical Performance Testing

Clinical performance testing was performed to substantiate subject device's equivalence. These studies included repeatability and reproducibility, qualitative image grading and agreement.

CIRRUS 6000 Repeatability and Reproducibility (R&R)

This was a prospective, multi-site study. A total of 117 subjects were enrolled: 27 without ocular pathology (normal), 37 with glaucoma, 30 with retinal pathology, and 23 with status post refractive surgery or with corneal pathology. 9 subjects were disqualified because they did not meet the inclusion/exclusion or were disqualified after scans due to the presence of macular changes due to drusen. The subject age range was 20-90, with a mean

age of 53.9 ± 12.4 for the normal sub-group, 71.2 ± 10.0 for the glaucoma subgroup, 73.0 ± 11.3 for the retinal pathology subgroup, 66.9 ± 15.9 for the cornea subgroup. The study population was composed of 46 (42.6%) females and 62 (57.4%) male subjects. 18 (16.7%) subjects were Asian, 5 (4.6%) subjects were Black, 79 (73.1%) subjects were Caucasian, and 6 (5.6%) subjects were listed as "Other". 96.0% of CIRRUS 6000 and 94.9% of CIRRUS 5000 scans acquired were valid and analyzed. Acquired scans were invalidated due to poor image quality (1.2-1.3%), scan decentration (1.7-2.4%), eye did not meet inclusion/exclusion criteria (1.1%), poor signal strength (0.1%), or algorithm failure (0.2%).

Three acceptable scans of each scan type were acquired on each of the study devices (three CIRRUS 6000 and three CIRRUS 5000 devices) with assigned operator/device pairs. Analysis of variance was performed to determine the repeatability and reproducibility as well as the variance associated with the combination of operator and device. Agreement between CIRRUS 5000 and CIRRUS 6000 was evaluated with Bland-Altman Limits of Agreement, and Deming Regression analysis methods.

The CIRRUS 6000 (C6000) R&R results are presented in the tables below:

Table 3. C6000 Macular Cube 512x128 Macular Thickness scans, Normal Subjects (n=225 scans), Precision Summary

Variable	Mean	DevOp SD	Residual SD	Repeat. %CV	Repeat. Limit	Repro. SD	Repro. %CV	Repro. Limit
Ganglion Cell Thickness								
Average Thickness (µm)	82.1	0.20	0.41	0.5%	1.1	0.48	0.6%	1.3
Temporal Superior (µm)	81.2	0.13	0.65	0.8%	1.8	0.79	1.0%	2.2
Superior (µm)	82.6	0.36	0.72	0.9%	2.0	0.82	1.0%	2.3
Nasal Superior (µm)	83.8	0.39	0.74	0.9%	2.1	0.92	1.1%	2.6
Nasal Inferior (µm)	81.9	0.25	0.70	0.8%	1.9	0.80	1.0%	2.2
Inferior (µm)	80.3	0.33	0.78	1.0%	2.2	0.87	1.1%	2.4
Temporal Inferior (µm)	82.8	0.12	0.69	0.8%	1.9	0.85	1.0%	2.4
Minimum Thickness (µm)	80.6	0.14	0.80	1.0%	2.2	0.86	1.1%	2.4
Macular Thickness								
Central Subfield (µm)	267.8	0.031	1.0	0.4%	2.9	2.0	0.7%	5.6
Inner Temporal (µm)	316.2	0.91	1.2	0.4%	3.4	2.5	0.8%	7.1
Inner Superior (µm)	329.3	0.76	1.3	0.4%	3.8	2.4	0.7%	6.6
Inner Nasal (µm)	331.4	0.81	1.2	0.4%	3.3	2.3	0.7%	6.5
Inner Inferior (µm)	325.4	0.24	1.2	0.4%	3.3	2.3	0.7%	6.5
Outer Temporal (µm)	265.3	1.3	1.3	0.5%	3.6	2.4	0.9%	6.9
Outer Superior (µm)	284.2	1.1	1.1	0.4%	3.1	2.0	0.7%	5.6
Outer Nasal (µm)	303.1	0.98	0.95	0.3%	2.7	2.0	0.7%	5.7
Outer Inferior (µm)	270.7	1.1	1.3	0.5%	3.5	2.4	0.9%	6.7

Variable	Mean	DevOp SD	Residual SD	Repeat. %CV	Repeat. Limit	Repro. SD	Repro. %CV	Repro. Limit
Average Cube Thickness (µm)	285.2	1.0	1.3	0.5%	3.7	2.0	0.7%	5.5
Volume Cube (mm3)	10.3	0.032	0.052	0.5%	0.15	0.077	0.8%	0.22

Reproducibility is the sum of: Residual, DevOp, and Subject:DevOp variance components.
Repeatability and reproducibility limits are 2.8 · SD.
%CV is calculated as 100*SD/Mean.

Table 4. C6000 Optic Disc Cube 200x200 RNFL Thickness scans, Normal Subjects (n=214 scans), Precision Summary

Variable	Mean	DevOp SD	Residual SD	Repeat. %CV	Repeat. Limit	Repro. SD	Repro. %CV	Repro. Limit
ONH								
Rim Area (mm2)	1.3	0.004	0.063	4.9%	0.18	0.084	6.6%	0.24
Disc Area (mm2)	1.8	0.000	0.11	6.4%	0.32	0.16	8.7%	0.43
Average Cup/Disc Ratio	0.51	0.000	0.018	3.6%	0.052	0.022	4.3%	0.061
Vertical C/D Ratio	0.48	0.005	0.024	5.0%	0.067	0.028	5.7%	0.078
Cup Volume (mm3)	0.15	0.000	0.007	4.5%	0.018	0.008	5.2%	0.022
RNFL Thickness								
Average RNFL Thickness (µm)	95.9	0.54	1.2	1.2%	3.3	1.7	1.8%	4.9
Temporal (µm)	64.9	0.24	2.1	3.3%	5.9	2.6	4.0%	7.3
Superior (µm)	118.6	1.7	2.7	2.3%	7.6	4.3	3.7%	12.2
Nasal (µm)	74.8	0.63	2.1	2.8%	5.9	2.9	3.9%	8.2
Inferior (µm)	125.2	0.55	2.8	2.2%	7.8	3.3	2.6%	9.3
Clock hour 1 (µm)	107.9	2.8	3.7	3.4%	10.3	5.9	5.4%	16.4
Clock hour 2 (µm)	92.7	0.000	3.6	3.9%	10.2	5.2	5.6%	14.6
Clock hour 3 (µm)	60.7	1.4	2.4	4.0%	6.8	3.7	6.1%	10.4
Clock hour 4 (µm)	70.9	0.66	2.9	4.1%	8.1	4.1	5.8%	11.6
Clock hour 5 (µm)	102.4	0.48	3.1	3.0%	8.6	4.4	4.3%	12.2
Clock hour 6 (µm)	139.2	0.000	4.8	3.4%	13.3	5.6	4.0%	15.6
Clock hour 7 (µm)	134.1	0.000	4.4	3.3%	12.4	5.8	4.3%	16.3
Clock hour 8 (µm)	63.6	0.000	2.6	4.1%	7.3	3.3	5.1%	9.1
Clock hour 9 (µm)	51.4	0.000	1.9	3.7%	5.3	2.4	4.6%	6.6
Clock hour 10 (µm)	79.7	0.55	2.7	3.4%	7.7	3.9	4.9%	10.9

Variable	Mean	DevOp SD	Residual SD	Repeat. %CV	Repeat. Limit	Repro. SD	Repro. %CV	Repro. Limit
Clock hour 11 (µm)	130.4	0.000	3.8	2.9%	10.6	4.8	3.7%	13.5
Clock hour 12 (µm)	117.5	2.1	4.1	3.5%	11.4	6.5	5.6%	18.3

Reproducibility is the sum of: Residual, DevOp, and Subject:DevOp variance components.
Repeatability and reproducibility limits are 2.8 · SD.
%CV is calculated as 100*SD/Mean.

Table 5. C6000 Pachymetry Thickness scans, Normal Subjects (n=207 scans), Precision Summary

Variable	Mean	DevOp SD	Residual SD	Repeat. %CV	Repeat. Limit	Repro. SD	Repro. %CV	Repro. Limit
Epithelial Thickness								
Central (µm)	49.1	0.000	0.90	1.8%	2.5	1.8	3.8%	5.2
Inner Nasal (µm)	48.1	0.22	1.2	2.6%	3.5	2.2	4.6%	6.2
Inner SuperoNasal (µm)	47.6	0.55	1.2	2.5%	3.4	2.1	4.4%	5.8
Inner Superior (µm)	46.6	0.26	1.2	2.7%	3.5	2.0	4.2%	5.5
Inner SuperoTemporal (µm)	46.5	0.000	1.1	2.5%	3.2	2.1	4.6%	6.0
Inner Temporal (µm)	47.0	0.000	1.1	2.4%	3.1	2.1	4.5%	5.9
Inner InferoTemporal (µm)	47.9	0.000	1.1	2.3%	3.1	2.3	4.9%	6.6
Inner Inferior (µm)	48.6	0.34	1.1	2.3%	3.1	2.6	5.3%	7.2
Inner InferoNasal (µm)	48.5	0.47	1.1	2.2%	3.1	2.5	5.1%	7.0
Middle Nasal (µm)	46.9	0.000	1.3	2.7%	3.6	2.5	5.3%	6.9
Middle SuperoNasal (µm)	45.6	0.27	1.5	3.3%	4.2	2.0	4.4%	5.7
Middle Superior (µm)	43.5	0.17	1.6	3.6%	4.4	1.9	4.3%	5.3
Middle SuperoTemporal (µm)	43.8	0.30	1.4	3.2%	3.9	1.9	4.4%	5.4
Middle Temporal (µm)	45.4	0.000	1.3	2.8%	3.6	2.3	5.0%	6.4
Middle InferoTemporal (µm)	47.0	0.25	1.2	2.6%	3.4	2.7	5.7%	7.5
Middle Inferior (µm)	47.3	0.45	0.99	2.1%	2.8	2.5	5.2%	6.9
Middle InferoNasal (µm)	46.9	0.001	1.2	2.5%	3.3	2.8	5.9%	7.7
Outer Nasal (µm)	47.5	0.000	1.5	3.2%	4.3	2.5	5.4%	7.1
Outer SuperoNasal (µm)	44.1	0.000	2.4	5.5%	6.9	2.8	6.3%	7.7
Outer Superior (µm)	40.9	0.000	1.8	4.5%	5.2	2.0	4.9%	5.6
Outer SuperoTemporal (µm)	41.3	0.000	2.1	5.2%	6.0	2.5	6.0%	6.9

Variable	Mean	DevOp SD	Residual SD	Repeat. %CV	Repeat. Limit	Repro. SD	Repro. %CV	Repro. Limit
Outer Temporal (µm)	44.5	0.000	1.4	3.1%	3.8	2.4	5.4%	6.7
Outer InferoTemporal (µm)	46.9	0.000	1.7	3.6%	4.7	2.9	6.1%	8.0
Outer Inferior (µm)	45.6	0.000	1.0	2.3%	2.9	2.8	6.0%	7.7
Outer InferoNasal (µm)	46.4	0.000	2.0	4.3%	5.6	3.1	6.8%	8.8
Pachymetry Thickness								
Central (µm)	543.3	0.000	1.2	0.2%	3.2	2.0	0.4%	5.5
Inner Nasal (µm)	566.0	0.27	2.5	0.4%	6.9	3.1	0.5%	8.7
Inner SuperoNasal (µm)	571.6	1.8	2.8	0.5%	7.8	3.8	0.7%	10.6
Inner Superior (µm)	570.9	2.4	3.2	0.6%	9.1	4.4	0.8%	12.3
Inner SuperoTemporal (µm)	559.1	1.4	2.3	0.4%	6.4	3.2	0.6%	8.8
Inner Temporal (µm)	547.6	0.000	1.6	0.3%	4.4	2.4	0.4%	6.8
Inner InferoTemporal (µm)	548.0	1.2	2.1	0.4%	5.8	3.4	0.6%	9.6
Inner Inferior (µm)	556.0	1.5	3.0	0.5%	8.4	4.4	0.8%	12.3
Inner InferoNasal (µm)	562.1	1.2	2.8	0.5%	7.8	4.0	0.7%	11.1
Outer Nasal (µm)	599.8	1.2	3.7	0.6%	10.3	4.7	0.8%	13.2
Outer SuperoNasal (µm)	609.6	3.3	4.9	0.8%	13.8	7.1	1.2%	20.0
Outer Superior (µm)	610.4	4.7	6.0	1.0%	16.9	8.9	1.5%	24.8
Outer SuperoTemporal (µm)	590.6	2.1	4.0	0.7%	11.2	5.0	0.9%	14.1
Outer Temporal (µm)	568.2	0.000	2.5	0.4%	7.0	3.3	0.6%	9.4
Outer InferoTemporal (µm)	570.4	0.000	3.6	0.6%	10.0	8.5	1.5%	23.9
Outer Inferior (µm)	585.2	1.7	4.4	0.8%	12.4	7.9	1.3%	22.0
Outer InferoNasal (µm)	594.7	1.6	4.0	0.7%	11.3	5.5	0.9%	15.5

Reproducibility is the sum of: Residual, DevOp, and Subject:DevOp variance components.
Repeatability and reproducibility limits are 2.8 · SD.
%CV is calculated as 100*SD/Mean.

Table 6. C6000 Macular Cube 512x128 Macular Thickness scans, Glaucoma Subjects (n=271 scans), Precision Summary

Variable	Mean	DevOp SD	Residal SD	Repeat. %CV	Repeat. Limit	Repro. SD	Repro. %CV	Repro. Limit
Ganglion Cell Thickness								

Variable	Mean	DevOp SD	Residal SD	Repeat. %CV	Repeat. Limit	Repro. SD	Repro. %CV	Repro. Limit
Average Thickness (µm)	61.5	0.000	0.82	1.3%	2.3	0.98	1.6%	2.7
Temporal Superior (µm)	62.1	0.000	1.2	2.0%	3.4	1.5	2.4%	4.1
Superior (µm)	62.5	0.000	2.3	3.7%	6.5	2.5	4.0%	7.0
Nasal Superior (µm)	64.1	0.000	1.4	2.1%	3.8	1.8	2.8%	5.1
Nasal Inferior (µm)	61.5	0.000	0.86	1.4%	2.4	1.1	1.7%	3.0
Inferior (µm)	58.7	0.000	1.4	2.5%	4.0	1.6	2.7%	4.5
Temporal Inferior (µm)	60.1	0.056	0.93	1.6%	2.6	1.1	1.8%	3.0
Minimum Thickness (µm)	55.4	0.000	2.1	3.7%	5.8	2.1	3.7%	5.8
Macular Thickness								
Central Subfield (µm)	262.5	0.000	1.3	0.5%	3.5	1.6	0.6%	4.5
Inner Temporal (µm)	289.2	0.39	1.6	0.6%	4.6	2.0	0.7%	5.6
Inner Superior (µm)	300.4	0.34	1.8	0.6%	4.9	2.0	0.7%	5.7
Inner Nasal (µm)	308.1	0.40	1.5	0.5%	4.2	1.8	0.6%	5.1
Inner Inferior (µm)	292.2	0.000	1.7	0.6%	4.8	2.0	0.7%	5.6
Outer Temporal (µm)	242.7	0.56	1.6	0.6%	4.4	2.0	0.8%	5.5
Outer Superior (µm)	256.3	0.64	1.5	0.6%	4.2	1.8	0.7%	5.1
Outer Nasal (µm)	269.8	0.74	1.5	0.6%	4.2	1.9	0.7%	5.4
Outer Inferior (µm)	239.5	0.76	1.5	0.6%	4.1	2.0	0.8%	5.6
Average Cube Thickness (µm)	256.8	0.8	1.4	0.6%	4.0	2.1	0.8%	6.0
Volume Cube (mm3)	9.2	0.026	0.057	0.6%	0.16	0.075	0.8%	0.21

Reproducibility is the sum of: Residual, DevOp, and Subject:DevOp variance components.
Repeatability and reproducibility limits are 2.8 · SD.
%CV is calculated as 100*SD/Mean.

Table 7. C6000 Optic Disc Cube 200x200 RNFL Thickness scans, Glaucoma Subjects (n=260 scans), Precision Summary

Variable	Mean	DevOp SD	Residual SD	Repeat. %CV	Repeat. Limit	Repro. SD	Repro. %CV	Repro. Limit
ONH								
Rim Area (mm2)	0.81	0.000	0.062	7.6%	0.17	0.063	7.7%	0.18
Disc Area (mm2)	1.7	0.000	0.12	7.2%	0.34	0.12	7.2%	0.34
Average Cup/Disc Ratio	0.68	0.000	0.013	1.9%	0.036	0.014	2.0%	0.039

Variable	Mean	DevOp SD	Residual SD	Repeat. %CV	Repeat. Limit	Repro. SD	Repro. %CV	Repro. Limit
Vertical C/D Ratio	0.71	0.003	0.021	2.9%	0.058	0.023	3.2%	0.063
Cup Volume (mm3)	0.37	0.000	0.029	7.8%	0.082	0.029	7.8%	0.082
RNFL Thickness								
Average RNFL Thickness (µm)	70.3	0.45	1.3	1.9%	3.7	1.7	2.4%	4.7
Temporal (µm)	50.1	0.30	1.6	3.1%	4.4	1.8	3.7%	5.2
Superior (µm)	83.6	0.96	2.5	3.0%	7.0	3.0	3.6%	8.4
Nasal (µm)	67.5	0.000	2.3	3.4%	6.4	3.0	4.4%	8.3
Inferior (µm)	80.3	0.73	2.6	3.2%	7.3	3.3	4.1%	9.1
Clock hour 1 (µm)	78.7	1.1	3.4	4.4%	9.6	4.4	5.5%	12.2
Clock hour 2 (µm)	75.0	0.000	3.5	4.6%	9.7	4.0	5.4%	11.3
Clock hour 3 (µm)	64.1	0.41	2.7	4.2%	7.6	3.4	5.3%	9.6
Clock hour 4 (µm)	63.3	0.000	2.9	4.5%	8.0	3.6	5.7%	10.1
Clock hour 5 (µm)	74.0	0.68	2.9	3.9%	8.1	4.1	5.5%	11.4
Clock hour 6 (µm)	87.9	0.94	4.4	5.0%	12.4	5.2	6.0%	14.7
Clock hour 7 (µm)	78.9	0.24	3.4	4.3%	9.5	4.1	5.2%	11.6
Clock hour 8 (µm)	49.0	0.39	2.6	5.3%	7.3	3.2	6.5%	8.9
Clock hour 9 (µm)	44.2	0.000	1.6	3.6%	4.4	2.1	4.7%	5.8
Clock hour 10 (µm)	56.9	0.41	2.5	4.4%	7.0	2.5	4.4%	7.1
Clock hour 11 (µm)	84.2	0.000	3.6	4.3%	10.1	4.4	5.3%	12.4
Clock hour 12 (µm)	87.9	1.5	4.7	5.4%	13.2	5.1	5.8%	14.2

Reproducibility is the sum of: Residual, DevOp, and Subject:DevOp variance components.
Repeatability and reproducibility limits are 2.8 · SD.
%CV is calculated as 100*SD/Mean.

Table 8. C6000 Pachymetry Thickness scans, Glaucoma Subjects (n=254 scans), Precision Summary

Variable	Mean	DevOp SD	Residual SD	Repeat. %CV	Repeat. Limit	Repro. SD	Repro. %CV	Repro. Limit
Epithelial Thickness								
Central (µm)	47.0	0.000	1.5	3.2%	4.2	1.9	4.1%	5.3
Inner Nasal (µm)	45.3	0.000	1.6	3.5%	4.5	2.3	5.0%	6.3
Inner SuperoNasal (µm)	44.8	0.000	1.7	3.8%	4.8	2.2	5.0%	6.3
Inner Superior (µm)	44.2	0.21	1.5	3.4%	4.2	2.0	4.5%	5.5

Variable	Mean	DevOp SD	Residual SD	Repeat. %CV	Repeat. Limit	Repro. SD	Repro. %CV	Repro. Limit
Inner SuperoTemporal (µm)	44.2	0.000	1.7	3.8%	4.7	2.1	4.7%	5.8
Inner Temporal (µm)	44.8	0.000	1.9	4.3%	5.3	2.5	5.5%	6.9
Inner InferoTemporal (µm)	45.9	0.000	1.9	4.2%	5.4	2.6	5.7%	7.3
Inner Inferior (µm)	47.0	0.27	2.0	4.3%	5.6	2.5	5.4%	7.1
Inner InferoNasal (µm)	46.5	0.000	1.9	4.1%	5.4	2.4	5.1%	6.7
Middle Nasal (µm)	44.2	0.000	1.6	3.5%	4.4	2.2	5.0%	6.2
Middle SuperoNasal (µm)	43.5	0.000	2.7	6.2%	7.5	3.1	7.0%	8.6
Middle Superior (µm)	41.8	0.000	1.7	4.1%	4.8	2.3	5.5%	6.4
Middle SuperoTemporal (µm)	42.1	0.000	1.7	4.1%	4.9	2.1	5.1%	6.0
Middle Temporal (µm)	43.5	0.000	2.0	4.5%	5.5	2.6	6.0%	7.3
Middle InferoTemporal (µm)	45.5	0.000	2.0	4.5%	5.7	2.7	6.0%	7.7
Middle Inferior (µm)	46.4	0.000	1.9	4.2%	5.4	2.4	5.3%	6.8
Middle InferoNasal (µm)	45.7	0.000	2.1	4.5%	5.8	2.4	5.4%	6.9
Outer Nasal (µm)	45.4	0.43	2.7	5.8%	7.4	3.0	6.6%	8.4
Outer SuperoNasal (µm)	42.8	0.000	2.2	5.2%	6.2	2.8	6.5%	7.8
Outer Superior (µm)	40.5	0.000	2.4	6.0%	6.8	3.1	7.6%	8.6
Outer SuperoTemporal (µm)	40.6	0.000	2.2	5.4%	6.1	2.5	6.1%	6.9
Outer Temporal (µm)	43.6	0.001	2.4	5.4%	6.6	2.7	6.1%	7.5
Outer InferoTemporal (µm)	46.6	0.000	2.4	5.1%	6.6	2.8	6.0%	7.8
Outer Inferior (µm)	46.2	0.000	2.0	4.3%	5.6	2.5	5.3%	6.9
Outer InferoNasal (µm)	46.3	0.54	2.1	4.5%	5.8	2.8	5.9%	7.7
Pachymetry Thickness								
Central (µm)	507.5	0.35	1.8	0.3%	5.0	2.4	0.5%	6.6
Inner Nasal (µm)	526.5	0.24	2.9	0.5%	8.0	3.6	0.7%	10.1
Inner SuperoNasal (µm)	533.4	1.4	3.8	0.7%	10.5	4.8	0.9%	13.5
Inner Superior (µm)	534.8	1.9	4.1	0.8%	11.6	5.3	1.0%	14.9
Inner SuperoTemporal (µm)	524.1	1.4	3.0	0.6%	8.5	4.1	0.8%	11.4
Inner Temporal (µm)	512.2	0.000	2.1	0.4%	6.0	2.8	0.5%	7.8
Inner InferoTemporal (µm)	513.5	0.83	2.7	0.5%	7.6	3.6	0.7%	10.1

Variable	Mean	DevOp SD	Residual SD	Repeat. %CV	Repeat. Limit	Repro. SD	Repro. %CV	Repro. Limit
Inner Inferior (µm)	521.3	0.86	3.2	0.6%	8.9	4.2	0.8%	11.6
Inner InferoNasal (µm)	524.2	0.83	3.1	0.6%	8.6	3.9	0.8%	11.0
Outer Nasal (µm)	556.3	1.3	3.9	0.7%	10.9	4.8	0.9%	13.6
Outer SuperoNasal (µm)	569.0	3.2	5.4	0.9%	15.1	7.6	1.3%	21.4
Outer Superior (µm)	574.8	3.4	6.0	1.0%	16.7	8.5	1.5%	23.9
Outer SuperoTemporal (µm)	556.5	1.5	4.4	0.8%	12.2	5.6	1.0%	15.5
Outer Temporal (µm)	532.0	0.000	2.6	0.5%	7.4	3.5	0.7%	9.9
Outer InferoTemporal (µm)	536.6	1.1	3.7	0.7%	10.3	5.5	1.0%	15.4
Outer Inferior (µm)	552.7	1.9	4.1	0.7%	11.6	6.0	1.1%	16.9
Outer InferoNasal (µm)	554.9	1.7	3.8	0.7%	10.6	5.6	1.0%	15.6

Reproducibility is the sum of: Residual, DevOp, and Subject:DevOp variance components.
Repeatability and reproducibility limits are 2.8 · SD.
%CV is calculated as 100*SD/Mean.

Table 9. C6000 Macular Cube 512x128 Macular Thickness scans, Retina Subjects (n=260 scans), Precision Summary

Variable	Mean	DevOp SD	Residual SD	Repeat. %CV	Repeat. Limit	Repro. SD	Repro. %CV	Repro. Limit
Ganglion Cell Thickness								
Average Thickness (µm)	71.5	0.000	4.0	5.6%	11.2	4.4	6.1%	12.2
Temporal Superior (µm)	75.9	0.000	3.9	5.1%	10.8	4.4	5.8%	12.4
Superior (µm)	66.7	0.000	4.9	7.3%	13.7	5.7	8.6%	16.0
Nasal Superior (µm)	73.4	0.000	5.2	7.1%	14.7	5.6	7.6%	15.7
Nasal Inferior (µm)	73.1	0.000	4.2	5.8%	11.9	4.6	6.3%	13.0
Inferior (µm)	67.4	0.000	5.0	7.5%	14.1	5.6	8.3%	15.6
Temporal Inferior (µm)	72.2	0.000	4.6	6.3%	12.8	4.7	6.6%	13.3
Minimum Thickness (µm)	54.7	0.000	6.9	12.5%	19.2	7.4	13.5%	20.7
Macular Thickness								
Central Subfield (µm)	274.2	0.31	2.4	0.9%	6.6	2.6	1.0%	7.3
Inner Temporal (µm)	310.7	0.82	1.9	0.6%	5.2	2.3	0.7%	6.4
Inner Superior (µm)	315.3	0.42	2.2	0.7%	6.3	2.4	0.8%	6.8
Inner Nasal (µm)	326.0	0.71	1.8	0.6%	5.1	2.3	0.7%	6.5
Inner Inferior (µm)	312.4	0.32	1.6	0.5%	4.5	2.0	0.7%	5.7

Outer Temporal (µm)	269.4	1.1	1.4	0.5%	4.0	2.1	0.8%	5.8
Outer Superior (µm)	275.9	0.33	1.4	0.5%	4.1	2.0	0.7%	5.6
Outer Nasal (µm)	293.7	0.57	1.1	0.4%	3.0	1.5	0.5%	4.2
Outer Inferior (µm)	265.1	0.95	1.3	0.5%	3.7	2.0	0.7%	5.5
Average Cube Thickness (µm)	279.9	0.68	1.5	0.5%	4.2	1.9	0.7%	5.4
Volume Cube (mm3)	10.1	0.025	0.058	0.6%	0.16	0.072	0.7%	0.20

Reproducibility is the sum of: Residual, DevOp, and Subject:DevOp variance components.
Repeatability and reproducibility limits are 2.8 · SD.
%CV is calculated as 100*SD/Mean.

Table 10. C6000 Optic Disc Cube 200x200 RNFL Thickness scans, Retina Subjects (n=196 scans), Precision Summary

Variable	Mean	DevOp SD	Residual SD	Repeat. %CV	Repeat. Limit	Repro. SD	Repro. %CV	Repro. Limit
ONH								
Rim Area (mm2)	1.2	0.009	0.034	2.8%	0.095	0.039	3.2%	0.11
Disc Area (mm2)	1.8	0.014	0.046	2.7%	0.13	0.056	3.2%	0.16
Average Cup/Disc Ratio	0.50	0.001	0.012	2.4%	0.034	0.013	2.5%	0.036
Vertical C/D Ratio	0.51	0.000	0.022	4.4%	0.062	0.023	4.6%	0.065
Cup Volume (mm3)	0.16	0.001	0.008	5.1%	0.023	0.009	5.4%	0.025
RNFL Thickness								
Average RNFL Thickness (µm)	88.3	0.49	2.2	2.4%	6.1	2.4	2.7%	6.6
Temporal (µm)	64.7	0.31	2.8	4.3%	7.7	3.0	4.6%	8.3
Superior (µm)	106.7	0.80	3.5	3.3%	9.8	4.3	4.0%	11.9
Nasal (µm)	75.3	0.38	3.5	4.7%	9.8	4.0	5.3%	11.1
Inferior (µm)	106.7	0.000	4.4	4.1%	12.3	4.9	4.6%	13.6
Clock hour 1 (µm)	95.7	1.8	6.4	6.7%	17.9	6.7	7.0%	18.7
Clock hour 2 (µm)	88.6	0.000	4.5	5.1%	12.7	5.5	6.2%	15.3
Clock hour 3 (µm)	68.3	0.83	4.0	5.9%	11.2	4.9	7.2%	13.8
Clock hour 4 (µm)	68.9	0.65	5.6	8.1%	15.7	5.8	8.4%	16.2
Clock hour 5 (µm)	89.3	0.000	8.1	9.1%	22.6	9.1	10.2%	25.4
Clock hour 6 (µm)	119.5	1.0	5.3	4.5%	14.9	5.9	4.9%	16.4
Clock hour 7 (µm)	111.5	1.5	4.3	3.9%	12.2	5.4	4.8%	15.0
Clock hour 8 (µm)	64.0	1.4	4.2	6.6%	11.8	4.4	6.9%	12.4
Clock hour 9 (µm)	55.9	0.000	3.4	6.0%	9.4	3.9	7.0%	11.0
Clock hour 10 (µm)	74.2	0.000	2.4	3.3%	6.8	2.9	3.9%	8.1
Clock hour 11 (µm)	116.5	0.000	6.3	5.4%	17.6	7.6	6.5%	21.2
Clock hour 12 (µm)	107.9	1.4	4.9	4.6%	13.8	5.9	5.5%	16.6

Reproducibility is the sum of: Residual, DevOp, and Subject:DevOp variance components.
Repeatability and reproducibility limits are 2.8 · SD.
%CV is calculated as 100*SD/Mean.

Table 11. C6000 Pachymetry Thickness scans, Retina Subjects (n=211 scans), Precision Summary

Variable	Mean	DevOp SD	Residual SD	Repeat. %CV	Repeat. Limit	Repro. SD	Repro. %CV	Repro. Limit
Epithelial Thickness								
Central (µm)	48.5	0.25	1.7	3.6%	4.9	2.2	4.5%	6.1
Inner Nasal (µm)	47.3	0.49	1.9	4.1%	5.4	2.4	5.2%	6.8
Inner SuperoNasal (µm)	46.9	0.53	1.7	3.7%	4.9	2.2	4.7%	6.2
Inner Superior (µm)	45.7	0.25	1.6	3.4%	4.4	2.0	4.3%	5.6
Inner SuperoTemporal (µm)	45.9	0.000	1.7	3.8%	4.9	2.2	4.8%	6.2
Inner Temporal (µm)	46.9	0.18	1.9	4.1%	5.4	2.5	5.3%	6.9
Inner InferoTemporal (µm)	47.9	0.74	1.8	3.7%	5.0	2.5	5.3%	7.1
Inner Inferior (µm)	47.9	0.60	1.8	3.8%	5.1	2.5	5.2%	7.0
Inner InferoNasal (µm)	48.0	0.55	2.0	4.2%	5.6	2.5	5.3%	7.1
Middle Nasal (µm)	46.2	0.39	1.8	4.0%	5.1	2.2	4.7%	6.1
Middle SuperoNasal (µm)	45.2	0.66	1.7	3.8%	4.9	2.1	4.7%	6.0
Middle Superior (µm)	42.7	0.46	1.9	4.4%	5.3	2.0	4.7%	5.6
Middle SuperoTemporal (µm)	43.4	0.45	1.8	4.2%	5.1	2.2	5.1%	6.1
Middle Temporal (µm)	45.8	0.20	1.9	4.1%	5.2	2.4	5.2%	6.6
Middle InferoTemporal (µm)	46.6	0.66	2.0	4.2%	5.5	2.8	6.0%	7.8
Middle Inferior (µm)	46.7	0.50	1.7	3.5%	4.6	2.4	5.1%	6.7
Middle InferoNasal (µm)	46.7	0.61	1.6	3.4%	4.4	2.2	4.7%	6.2
Outer Nasal (µm)	47.0	0.000	1.7	3.6%	4.7	1.8	3.8%	4.9
Outer SuperoNasal (µm)	43.8	0.20	3.1	7.2%	8.8	3.4	7.7%	9.5
Outer Superior (µm)	40.1	0.000	1.9	4.7%	5.3	2.0	5.0%	5.6
Outer SuperoTemporal (µm)	41.0	0.27	2.0	5.0%	5.7	2.2	5.3%	6.1
Outer Temporal (µm)	44.9	0.000	1.9	4.3%	5.4	2.3	5.0%	6.3
Outer InferoTemporal (µm)	46.3	0.000	2.5	5.4%	7.0	2.8	6.1%	7.9
Outer Inferior (µm)	45.8	0.000	1.4	3.1%	4.0	1.9	4.2%	5.3
Outer InferoNasal (µm)	46.9	0.000	2.5	5.4%	7.1	2.6	5.6%	7.3
Pachymetry Thickness								
Central (µm)	537.4	0.000	1.9	0.3%	5.2	2.2	0.4%	6.1
Inner Nasal (µm)	561.4	0.000	3.2	0.6%	9.1	3.4	0.6%	9.6

Variable	Mean	DevOp SD	Residual SD	Repeat. %CV	Repeat. Limit	Repro. SD	Repro. %CV	Repro. Limit
Inner SuperoNasal (µm)	568.1	0.77	4.5	0.8%	12.5	5.1	0.9%	14.2
Inner Superior (µm)	567.6	1.2	4.9	0.9%	13.7	5.8	1.0%	16.2
Inner SuperoTemporal (µm)	554.0	0.61	3.9	0.7%	11.0	4.5	0.8%	12.5
Inner Temporal (µm)	541.4	0.000	2.4	0.4%	6.6	2.9	0.5%	8.2
Inner InferoTemporal (µm)	542.9	0.98	2.7	0.5%	7.6	4.0	0.7%	11.3
Inner Inferior (µm)	550.9	1.3	3.8	0.7%	10.7	4.7	0.9%	13.3
Inner InferoNasal (µm)	556.7	1.4	3.6	0.6%	10.1	4.3	0.8%	12.1
Outer Nasal (µm)	598.9	0.73	4.6	0.8%	12.8	5.3	0.9%	14.9
Outer SuperoNasal (µm)	611.3	1.7	6.1	1.0%	17.0	7.4	1.2%	20.7
Outer Superior (µm)	612.6	2.4	6.6	1.1%	18.4	9.0	1.5%	25.2
Outer SuperoTemporal (µm)	588.8	0.68	5.4	0.9%	15.2	6.5	1.1%	18.1
Outer Temporal (µm)	563.2	0.78	3.4	0.6%	9.7	4.2	0.7%	11.6
Outer InferoTemporal (µm)	567.6	2.3	4.4	0.8%	12.3	6.3	1.1%	17.6
Outer Inferior (µm)	584.7	3.5	5.7	1.0%	16.0	7.6	1.3%	21.4
Outer InferoNasal (µm)	592.2	2.2	5.1	0.9%	14.2	6.0	1.0%	16.7

Reproducibility is the sum of: Residual, DevOp, and Subject:DevOp variance components.
Repeatability and reproducibility limits are 2.8 · SD.
%CV is calculated as 100*SD/Mean.

Table 12. C6000 Pachymetry Thickness scans, Cornea Subjects (n=204 scans), Precision Summary

Variable	Mean	DevOp SD	Residual SD	Repeat. %CV	Repeat. Limit	Repro. SD	Repro. %CV	Repro. Limit
Epithelial Thickness								
Central (µm)	48.2	0.29	1.6	3.3%	4.5	2.3	4.8%	6.5
Inner Nasal (µm)	47.8	0.39	1.9	4.0%	5.4	2.7	5.6%	7.5
Inner SuperoNasal (µm)	47.0	0.41	2.0	4.2%	5.5	2.5	5.4%	7.1
Inner Superior (µm)	46.1	0.28	1.8	3.9%	5.1	2.4	5.2%	6.7
Inner SuperoTemporal (µm)	46.7	0.000	1.9	4.1%	5.4	2.4	5.0%	6.6
Inner Temporal (µm)	47.2	0.086	2.1	4.4%	5.8	2.4	5.1%	6.7
Inner InferoTemporal (µm)	48.1	0.000	2.1	4.3%	5.7	2.6	5.4%	7.3
Inner Inferior (µm)	49.3	0.000	1.4	2.9%	3.9	2.5	5.1%	7.1
Inner InferoNasal (µm)	48.9	0.34	1.8	3.8%	5.1	2.8	5.7%	7.7

Variable	Mean	DevOp SD	Residual SD	Repeat. %CV	Repeat. Limit	Repro. SD	Repro. %CV	Repro. Limit
Middle Nasal (µm)	45.7	0.000	1.9	4.2%	5.4	2.5	5.5%	7.0
Middle SuperoNasal (µm)	44.2	0.38	2.2	5.0%	6.2	2.7	6.0%	7.5
Middle Superior (µm)	42.0	0.21	2.1	4.9%	5.8	2.4	5.8%	6.8
Middle SuperoTemporal (µm)	43.5	0.15	2.0	4.5%	5.5	2.3	5.3%	6.4
Middle Temporal (µm)	45.6	0.000	2.5	5.4%	6.9	2.7	5.9%	7.6
Middle InferoTemporal (µm)	46.7	0.000	2.3	5.0%	6.6	2.7	5.7%	7.5
Middle Inferior (µm)	47.9	0.000	1.7	3.5%	4.7	2.7	5.6%	7.6
Middle InferoNasal (µm)	46.8	0.26	2.1	4.6%	6.0	2.8	5.9%	7.8
Outer Nasal (µm)	45.2	0.000	2.1	4.6%	5.8	2.6	5.7%	7.2
Outer SuperoNasal (µm)	43.0	0.000	3.0	7.0%	8.4	3.3	7.8%	9.4
Outer Superior (µm)	39.6	0.000	2.4	6.2%	6.8	2.7	6.8%	7.6
Outer SuperoTemporal (µm)	41.1	0.000	2.4	5.9%	6.8	2.5	6.1%	7.0
Outer Temporal (µm)	44.4	0.70	2.3	5.2%	6.4	2.6	5.9%	7.4
Outer InferoTemporal (µm)	45.9	0.000	3.3	7.2%	9.2	3.4	7.5%	9.6
Outer Inferior (µm)	45.4	0.000	2.3	5.1%	6.5	2.8	6.2%	7.9
Outer InferoNasal (µm)	46.5	0.001	4.3	9.2%	11.9	4.5	9.7%	12.6
Pachymetry Thickness								
Central (µm)	517.5	0.000	2.2	0.4%	6.1	2.4	0.5%	6.8
Inner Nasal (µm)	547.3	0.95	3.4	0.6%	9.6	3.9	0.7%	10.9
Inner SuperoNasal (µm)	551.9	0.13	3.9	0.7%	10.8	4.2	0.8%	11.8
Inner Superior (µm)	553.2	0.89	5.4	1.0%	15.0	6.0	1.1%	16.8
Inner SuperoTemporal (µm)	542.4	0.89	4.9	0.9%	13.8	5.6	1.0%	15.7
Inner Temporal (µm)	527.2	0.43	3.0	0.6%	8.4	3.8	0.7%	10.5
Inner InferoTemporal (µm)	528.3	1.9	4.0	0.8%	11.3	5.1	1.0%	14.4
Inner Inferior (µm)	538.3	2.8	5.3	1.0%	14.8	7.4	1.4%	20.6
Inner InferoNasal (µm)	543.7	2.3	5.5	1.0%	15.4	6.5	1.2%	18.2
Outer Nasal (µm)	589.9	0.000	4.4	0.7%	12.2	5.3	0.9%	14.9
Outer SuperoNasal (µm)	597.5	2.8	6.5	1.1%	18.1	8.1	1.4%	22.8
Outer Superior (µm)	601.4	2.2	9.6	1.6%	27.0	9.9	1.6%	27.7

Variable	Mean	DevOp SD	Residual SD	Repeat. %CV	Repeat. Limit	Repro. SD	Repro. %CV	Repro. Limit
Outer SuperoTemporal (µm)	582.0	0.28	7.7	1.3%	21.5	8.3	1.4%	23.1
Outer Temporal (µm)	555.8	1.3	3.8	0.7%	10.7	4.5	0.8%	12.7
Outer InferoTemporal (µm)	562.0	2.1	6.7	1.2%	18.8	7.3	1.3%	20.5
Outer Inferior (µm)	581.5	4.3	8.4	1.4%	23.5	12.6	2.2%	35.2
Outer InferoNasal (µm)	589.0	3.5	7.0	1.2%	19.5	9.4	1.6%	26.4

Reproducibility is the sum of: Residual, DevOp, and Subject:DevOp variance components.
Repeatability and reproducibility limits are 2.8 · SD.
%CV is calculated as 100*SD/Mean.

CIRRUS 6000 Angiography Image Quality Study

This was a multi-site prospective study. A total of 110 subjects aged 18 years or older were enrolled: 103 retinal diseased subjects, 7 normal subjects. Two subjects were disqualified because they did not meet the inclusion/exclusion criteria, eleven others were disqualified because the operator was unable to acquire quality study scans, and one subject was discontinued due to the inability to continue the study visit. Two subjects were disqualified due to lack of any CIRRUS 6000 scans acquired; and two subjects were discontinued because they did not return for their second study visit. 93 subjects had at least one valid OCT scan or valid FA/ICGA images. However, only 92 subjects had at least one valid OCT scan. The subject age range was 19-91, with a mean age of 66.0 ± 14.8. The study population was composed of 42 (45.2%) females and 51 (54.8%) male subjects. 15 (16.1%) subjects were Asian, 4 (4.3%) subjects were Black, 63 (67.7%) subjects were Caucasian, 1 (1.1%) subject was Native Hawaiian/ Pacific Islander, and 10 (10.8%) subjects were listed as "Other". 78.3% of CIRRUS 6000 and 77.2% of CIRRUS 5000 scans acquired were valid and analyzed. Acquired scans were invalidated due to duplicate scans (1.1-2.5%), eye did not meet inclusion/exclusion criteria (2.9-4.7%), poor image quality (7.6-10.6%), scan decentration (1.8-3.2%), poor signal strength (0.5-0.9%), or missing comparison photos (3.8-4.8%). Three independent reviewers from a reading center graded the OCTA scans on image quality and clinically relevant information according to pre-determined grading criteria. The proportion of Clinically Acceptable Overall Images was 0.98 or above for the CIRRUS 6000 device and 0.94 and above for the CIRRUS 5000 device for all subjects.

CIRRUS 6000 Raster Image Quality Study

This was a multi-site prospective study. A total of 68 subjects were enrolled: 20 subjects with normal eyes and 48 subjects with retinal disease. The subject age range was 27-92, with a mean age of 64.3 ± 15.4. The study population was composed of 36 (52.9%) females and 32 (47.1%) male subjects. 14 (20.6%) subjects were Asian, 6 (8.8%) subjects were Black, 39 (57.4%) subjects were Caucasian and 9 (13.2%) subjects were listed as "Other". 92.3% of CIRRUS 6000 and 91.3% of CIRRUS 5000 scans acquired were valid and analyzed. Acquired scans were invalidated due to duplicate scans (6.2-6.9%), eye did not meet inclusion/exclusion criteria (1.4%), poor image quality or blur (0.1-0.3%), or scan decentration (0.1%). Three independent graders from a reading center graded the raster B-scans on image quality and clinically relevant information according to pre-determined grading criteria. The proportion of Clinically Acceptable Overall Images was 1.00 for all scan types across the CIRRUS 6000 and the CIRRUS 5000 device for all subjects.

8. CONCLUSION

The indications for use are identical except for the removal of normative database for CIRRUS 6000 to the indications for use of the predicate device; and therefore, are determined to be substantially equivalent.

The technological characteristics and risk profile of the subject device are equivalent to the predicate device; and therefore, are determined to be substantially equivalent.

Testing methods are equivalent to those of the predicate device; and therefore, are determined to be substantially equivalent.

Therefore, the subject device meets the requirements for substantial equivalence as compared to the proposed predicate device.