February 15, 2019

Carl Zeiss Meditec, Inc.
Mandy Ambrecht
Senior Staff Regulatory Affairs Specialist
5160 Hacienda Drive
Dublin, CA 94568

Re: K181534
Trade/Device Name: Cirrus Hd-oct
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO, IYO, ITX
Dated: January 17, 2019
Received: January 18, 2019

Dear Mandy Ambrecht:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health
Sincerely,

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181534

Device Name
CIRRUS HD-OCT

Models 500, 5000

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. 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 is indicated as an aid in the visualization of vascular structures of the retina and choroid. (Model 5000 only.)

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.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
(per 21 CFR §807.92)

CIRRUS HD-OCT with Software Version 10

GENERAL INFORMATION

Manufacturer:	Carl Zeiss Meditec, Inc. 5160 Hacienda Drive Dublin, California 94568 (925) 557-4100 (phone) (925) 557-4259 (fax) Est. Reg. No. 2918630
Contact Person:	Mandy Ambrecht Senior Staff Regulatory Affairs Specialist Carl Zeiss Meditec, Inc. 5160 Hacienda Drive Dublin, California 94568 (925) 557-4561 (phone) (925) 557-4259 (fax)
Date Summary Prepared:	February 15, 2019
Classification name:	Tomography, Optical Coherence; Ophthalmoscope
Classification:	Class II (acc. 21 CFR 886.1570)
Product Code:	OBO
Trade/Proprietary name:	CIRRUS HD-OCT
Common or Usual name:	Optical Coherence Tomographer (OCT)
Models:	5000 / 500

PREDICATE DEVICE

Company: Primary Predicate Device:	Carl Zeiss Meditec, Inc. CIRRUS HD-OCT with Software Version 8 (K150977)
Company: Device:	Carl Zeiss Meditec, Inc. PLEX Elite 9000 SS-OCT (K161194)

REFERENCE DEVICE

Company:	ArcScan, Inc.
Device:	ArcScan Insight 100 (K153416)

INDICATIONS FOR USE (21 CFR §807.92(a)(5))

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 is indicated as an aid in the visualization of vascular structures of the retina and choroid. (Model 5000 only.)

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.

DEVICE DESCRIPTION (21 CFR §807.92(a)(4))

The CIRRUS™ HD-OCT 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. Using this non-invasive optical technique, CIRRUS HD-OCT produces high-resolution cross-sectional tomograms of the eye without contacting the eye. It also produces images of the retina and layers of the retina from an *en face* perspective (i.e., as if looking directly in the eye).

The CIRRUS HD-OCT is offered in two models, Model 5000 and 500. In the CIRRUS HD-OCT Model 5000, the fundus camera is a line scanning ophthalmoscope. The CIRRUS HD-OCT Model 500 is similar to the Model 5000 except that it provides the fundus image using the OCT scanner only.

The acquired imaging data can be analyzed to provide thickness and area measurements of regions of interest to the clinician. The system uses acquired data to determine the fovea location or the optic disc location. Measurements can then be oriented using the fovea and/or optic disc locations. The patient's results can be compared to subjects without disease for measurements of RNFL thickness, neuroretinal rim area, average and vertical cup-to-disc area ratio, cup volume, macular thickness and ganglion cell plus inner plexiform layer thickness.

In addition to macular and optic disc cube scans, the CIRRUS HD-OCT 5000 also offers scans

for OCT angiography imaging, a non-invasive approach with depth sectioning capability to visualize microvascular structures of the eye.

Anterior segment scans enable analysis of the anterior segment including Anterior Chamber Depth, Angle-to-Angle and automated measurement of the thickness of the cornea with the Pachymetry scan.

NEW FEATURES - ANTERIOR SEGMENT

Epithelial Thickness Mapping

The Pachymetry scan analysis was updated to include an automated, quantitative measurement of the corneal epithelium.

NEW FEATURES - POSTERIOR SEGMENT

Guided Progression Analysis (GPA) for Ganglion Cell with Inner Plexiform Layer

GPA was updated to follow changes to the thickness of the sum of the Ganglion Cell Layer + Inner Plexiform Layer (GCL/IPL). It compares Average GCL/IPL measurements from the Macular Cube 200x200 or 512x128 scan over time and determines if change over time has occurred that exceeds the test-retest variability. The analysis includes a chronological display of GCL/IPL thickness maps and thickness change maps, and a graphical plot of the Average GCL/IPL thickness as a function of patient age using the same layout as the graphical plots of RNFL average thickness measurements and Average Cup-to-Disc Ratio versus patient age.

Minimum Intensity (MinIP) Slab

The En Face analysis was expanded to include the Minimum Intensity Projection slab, referred to as “Min-IP”. Minimum intensity projection (Min-IP) is an en face visualization of the retina that identifies and displays the minimum optical intensity found between the internal limiting membrane and retinal pigment epithelium.

OCT Angiography Analysis (AngioPlex)

OCT Angiography Analysis was updated to better image retinal vasculature by using both intensity and phase data (referred to as OMAG Complex reconstruction or OMAG^{c}). An additional OCT angiography scan pattern was added to expand scanning from 6x6 to 8x8 mm. In addition, an option allows users the ability to edit layer segmentations for Angiography scans.

OCT Angiography (OCTA) Two Visit Comparison

The OCT Angiography Two Visit Comparison presents a side-by-side comparison of any two visits from a patient’s history.

Smart HD Scans previously available for the Model 5000 are now available for the Model 500:

- **HD 1 Line 100x1 - High-Definition Single Line Scan -** This scan generates a single high definition scan at a depth of 2.0 mm by averaging 100 B-scans, each composed of 1024 A-scans. The scan can be positioned anywhere on the fundus image.

- **HD 21 Line: 21 High-Definition Scan** - This scan generates 21 high-definition horizontal scan lines at a depth of 2.0 mm. The amount of B-scan averaging per line depends on the version of the instrument computer. The scan can be positioned anywhere on the fundus image.

- **HD Cross: 10 High-Definition Scan** - This scan generates five horizontal and five vertical high-definition scan lines at a depth of 2.0 mm. The scan can be positioned anywhere on the fundus image.

- **HD Radial: 12 High-Definition Radial Scans -** This scan generates 12 high-definition radial scan lines at a depth of 2.0. Scan rotation and line spacing are fixed. The scan can be positioned anywhere on the fundus image.

PERFORMANCE DATA & SUMMARY OF VERIFICATION AND VALIDATION ACTIVITY (21 CFR §807.92(B))

Electrical Safety Testing
The CIRRUS HD-OCT was assessed for conformity with the relevant requirements of ANSI/AAMI 60601-1: 2005+ A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance and was found to comply.

Electromagnetic Compatibility Testing
The CIRRUS HD-OCT was assessed for conformity with the relevant requirements of IEC 60601-1-2: Ed. 3 / 2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests and was found to comply.

System Level Verification
The system level testing verified that the device performed according to requirements.

DICOM Conformity Assessment
The DICOM Conformance Statement was provided.

Software Verification and Validation
Software documentation was provided in accordance with FDA’s software guidance documents. The results of verification and validation testing demonstrate that the software performs in accordance with its established requirements and will therefore meet user needs and intended uses.

TECHNOLOGICAL CHARACTERISTICS (21 CFR §807.92(a)(6)) AND SUBSTANTIAL EQUIVALENCE (21 CFR §807.92(a)(3))

It is the opinion of Carl Zeiss Meditec, Inc. that the proposed device, CIRRUS HD-OCT with Software Version 10.0, is substantially equivalent to the CIRRUS HD-OCT with Software Version 8.0 (K150977). Both devices are indicated for in-vivo viewing, axial cross-sectional, and three-dimensional imaging and measurement of anterior and posterior ocular structures. Both devices offer CIRRUS OCT angiography which is indicated as an aid in the visualization of vascular structures of the retina and choroid.

The technological characteristics of the proposed product, CIRRUS HD-OCT with Software Version 10.0, and the predicate device, CIRRUS HD-OCT with Software Version 8.0 (K150977), regarding design, material, and energy source are the same. The principle of operation between the proposed CIRRUS HD-OCT with Software Version 10.0 and the primary predicate device, CIRRUS HD-OCT with Software Version 8.0, is identical. Both devices employ a non-invasive, non-contact low-coherence interferometry technique to generate cross-sectional images of internal ocular tissue microstructures by measuring optical reflections from tissue. Both devices obtain high-resolution images using spectral domain optical coherence tomography. Both devices provide cross-sectional images of the anterior and posterior structures of the eye (i.e., retina, including the ganglion and retinal nerve fiber layers). Both devices can be used to image structures of the anterior segment by changing the focus of the OCT beam.

With the exception of an external keyboard, mouse and printer, both devices integrate all hardware components into a single unit, which includes the scan acquisition optics, the interferometer and spectrometer, and the system computer and video monitor.

Both devices use a beam of light, called a scanning super luminescent diode (SLD), to rapidly scan the eye in a non-contact manner to acquire very detailed cross-sectional images of various structures. Both devices utilize a central wavelength of 840 nanometers [0.8 microns (µm)] primarily designed to scan the back of the eye such as the retina and the optic nerve.

The difference between the predicate device and the proposed device lies within the features offered by the software. In the anterior segment, whereas the predicate device offered automated measurement of the central corneal thickness, the proposed device offers automated measurement of the corneal epithelium thickness.

It is also the opinion of Carl Zeiss Meditec, Inc. that the proposed device, CIRRUS HD-OCT with Software Version 10.0, is substantially equivalent to the predicate device, PLEX Elite 9000 Swept-Source (SS) OCT (K161194). Both devices are intended for in-vivo viewing, axial cross-sectional and three-dimensional imaging of posterior ocular structures. Both devices are computerized instruments that acquire cross-sectional tomograms of the posterior ocular structures (including cornea, retina, retinal nerve fiber layer, macula, and optic disc). Both devices employ non-invasive, non-contact, low-coherence interferometry to obtain these high-resolution images. Using this non-invasive optical technique, both devices produce high-resolution cross-sectional tomograms of the eye without contacting the eye. Both devices produce images of the retina and layers of the retina from an en face perspective (i.e., as if

looking directly in the eye) and non-contrast angiographic imaging of the retinal microvasculature. On both devices, OCT Angiography images are processed to provide detailed images of ocular blood flow without the use of intravenous dyes to visualize microvasculature structures of the eye. The flow data that is generated by processing OCT images with OMAGc has the same resolution and axial and transverse extent as the OCT intensity and phase data, and therefore depth resolved flow images can be generated and displayed.

A difference between the proposed device and the predicate device is that the PLEX Elite 9000 is a Swept Source OCT (SS-OCT) operating at 1060 nm whereas the CIRRUS HD-OCT with Software Version 8.0 is a Spectral Domain OCT (SD-OCT) operating at 840 nm.
It is also the opinion of CZMI that the CIRRUS HD-OCT with Software Version 10.0 is substantially equivalent to the reference device, ArcScan Insight 100 (K153416), with regard to the intended use. Both devices are indicated for imaging and measurement of ocular structures in the anterior segment. Both devices measure thickness of the cornea and cornea epithelium. Both devices measure anatomic structures such as the Anterior Chamber Depth and Angle-to-Angle Width.

A difference between the proposed device, and the previously cleared ArcScan Insight 100 is that the reference device uses very high frequency digital ultrasound whereas the CIRRUS HD-OCT uses spectral domain OCT. In addition, with the reference device, scans are performed under immersion whereas they are not with CIRRUS HD-OCT.

SUBSTANTIAL EQUIVALENCE

It is the opinion of Carl Zeiss Meditec, Incorporated that the CIRRUS HD-OCT with Software Version 10 is substantially equivalent to the CIRRUS HD-OCT with Software Version 8.0 (K150977) and PLEX Elite 9000 SS-OCT (K161194) and to the reference device, ArcScan Insight 100 (K153416). The indications for use for the CIRRUS HD-OCT with Software Version 10 is similar to the indications for the predicate devices and reference device cited in this application. A technological comparison and clinical testing demonstrate that the CIRRUS HD-OCT with Software Version 10 is functionally equivalent to the predicate devices.

Evaluation performed on the CIRRUS HD-OCT with Software Version 10 supports the indications for use statement and demonstrates that the device is substantially equivalent to the predicate devices and does not raise new questions regarding safety and effectiveness.

RISK MANAGEMENT

Risk management is ensured via a risk analysis, which is used to identify potential hazards and mitigations. These potential hazards are controlled by software means, user instructions, verification of requirements, and validation of the clinical workflow to ensure that the product meets its intended uses. Carl Zeiss Meditec, Inc. adheres to recognized and established industry practice and relevant international standards where indicated.

CLINICAL EVALUATION (21 CFR 807.92(b)(2))

Clinical data were collected and evaluated to support the indications for use statement for the CIRRUS HD-OCT with Software Version 10 and to demonstrate substantial equivalence to the CIRRUS HD-OCT with Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head and Ganglion Cell Normative Databases with software version 8.0. The study is summarized below.

Corneal Epithelial Thickness Measurements (Pachymetry Scans)

A clinical study was conducted to determine the repeatability and reproducibility of corneal epithelial thickness measurements on the CIRRUS HD-OCT Model 5000 using the pachymetry scan analysis and to compare agreement between automated and manual measurements.

The study enrolled 11 adult participants with normal corneas (Group 1) and 12 participants (Group 2) with either keratoconus (five participants) or who had previously undergone laser in-situ keratomileusis (LASIK; seven participants). To generate automated corneal epithelial thickness measurements, one eligible eye of each participant was scanned three times with the Pachymetry scan on each of three fixed CIRRUS HD-OCT device-operator combinations (Model 5000 with software version 10.0). The order of device-operator scanning was randomized. Scans were reviewed for adequate image quality after acquisition. Repeatability and reproducibility of the 25 sector thickness parameters were calculated using a crossed, random-effects analysis of variance (ANOVA) model. To generate manually marked corneal epithelial thickness measurements, three masked graders reviewed images and manually performed measurements in the 25 sectors. The automated corneal epithelial measurement obtained from the first qualified scan from each eligible study eye was used for comparison to manual measurements from that study eye. Measurement agreement was evaluated using Deming regression and Bland-Altman analyses.

Repeatability and reproducibility data for epithelial thickness measurements in all sectors is shown in Table 1 for Normal eyes and in Table 2 for eyes post-status LASIK or with keratoconus.

Results for Deming regression fits by Sector and Group are shown in Table 3. Deming regressions were carried out assuming equal variability in Manual and Algorithm measurements.

Results for Bland-Altman Limits of Agreement calculations by Sector and Group are shown in Table 4. For each Sector, and overall, the limits of Agreement were calculated as:
mean +/- 1.96 * SD, where “mean” is the mean of the differences between Algorithm and Manual results, and SD is the standard deviation. Confidence intervals for the LOAs were calculated using the approximation from Bland and Altman (1999).

Table 1
Repeatability and Reproducibility of OCT Epithelial Thickness
(Normal Eyes)

Parameter	Mean (µm)	Repeatability			Reproducibility		
		SD (µm)	Limit (µm)	Mean (µm)	SD (µm)	Limit (µm)	Mean (µm)
Central	49.6	0.8	2.2	1.6	1.1	3.2	2.3
Inner Nasal	48.9	1.0	2.9	2.1	1.3	3.6	2.6
Inner SuperoNasal	47.8	1.3	3.7	2.8	1.5	4.1	3.1
Inner Superior	47.2	1.3	3.6	2.7	1.5	4.1	3.1
Inner SuperoTemporal	47.1	1.4	3.9	2.9	1.5	4.1	3.1
Inner Temporal	47.5	1.2	3.5	2.6	1.5	4.1	3.1
Inner InferoTemporal	48.8	1.3	3.6	2.7	1.4	4.0	2.9
Inner Inferior	50.3	1.1	3.1	2.2	1.4	3.9	2.8
Inner InferoNasal	50.1	1.0	2.7	1.9	1.2	3.3	2.4
Middle Nasal	47.3	1.0	2.7	2.0	1.1	3.0	2.3
Middle SuperoNasal	46.5	1.5	4.3	3.3	1.6	4.5	3.4
Middle Superior	44.8	1.6	4.4	3.5	1.6	4.5	3.6
Middle SuperoTemporal	45.1	1.5	4.1	3.2	1.5	4.1	3.2
Middle Temporal	45.4	1.3	3.7	2.9	1.4	4.0	3.1
Middle InferoTemporal	47.4	1.1	3.1	2.4	1.2	3.2	2.4
Middle Inferior	48.9	1.2	3.4	2.5	1.3	3.6	2.7
Middle InferoNasal	48.6	1.1	3.1	2.3	1.2	3.2	2.4
Outer Nasal	47.1	1.0	2.9	2.2	1.2	3.3	2.5
Outer SuperoNasal	45.2	1.8	5.0	4.0	1.8	5.0	4.0
Outer Superior	41.9	1.8	5.2	4.4	1.9	5.3	4.5
Outer SuperoTemporal	43.8	1.7	4.8	3.9	1.8	5.1	4.1
Outer Temporal	44.8	1.2	3.3	2.6	1.3	3.6	2.8
Outer InferoTemporal	47.3	1.4	3.9	3.0	1.6	4.5	3.4
Outer Inferior	48.0	1.4	3.9	2.9	1.5	4.1	3.1
Outer InferoNasal	47.6	1.4	4.0	3.0	1.5	4.1	3.1

All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.
Mean = Intercept of the ANOVA model
Repeatability SD = Square root of the residual variance.
Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance.
Repeatability limit = 2.8 x Repeatability SD.
Reproducibility limit = 2.8 x Reproducibility SD.
Repeatability CV% = (Repeatability SD)/Mean x 100%.
Reproducibility CV% = (Reproducibility SD)/Mean x 100%.

Table 2
Repeatability and Reproducibility of OCT Epithelial Thickness
(Keratoconus or Post-LASIK Eyes)

Parameter	Mean (µm)	Repeatability			Reproducibility		
		SD (µm)	Limit (µm)	CV (%)	SD (µm)	Limit (µm)	CV (%)
Central	47.7	1.4	4.0	3.0	1.8	5.1	3.8
Inner Nasal	49.1	1.6	4.4	3.2	2.1	5.9	4.3
Inner SuperoNasal	48.6	1.5	4.3	3.1	1.9	5.4	4.0
Inner Superior	47.7	1.7	4.8	3.6	2.1	5.9	4.5
Inner SuperoTemporal	46.7	1.8	5.2	3.9	2.3	6.4	4.9
Inner Temporal	46.5	1.9	5.4	4.2	2.3	6.4	4.9
Inner InferoTemporal	47.3	2.1	5.8	4.4	2.5	7.0	5.3
Inner Inferior	48.2	1.9	5.4	4.0	2.6	7.2	5.4
Inner InferoNasal	49.0	1.8	5.0	3.6	2.3	6.4	4.7
Middle Nasal	47.4	1.7	4.7	3.6	2.6	7.2	5.4
Middle SuperoNasal	46.5	1.6	4.6	3.5	2.3	6.4	4.9
Middle Superior	44.9	1.7	4.9	3.9	2.1	5.9	4.7
Middle SuperoTemporal	44.8	1.9	5.4	4.3	2.4	6.7	5.4
Middle Temporal	45.8	2.5	6.9	5.4	2.6	7.4	5.8
Middle InferoTemporal	46.6	2.7	7.4	5.7	3.2	8.9	6.8
Middle Inferior	46.6	2.4	6.8	5.2	3.6	10.0	7.7
Middle InferoNasal	47.7	2.0	5.7	4.3	3.0	8.3	6.2
Outer Nasal	46.9	1.8	5.1	3.9	2.8	7.8	5.9
Outer SuperoNasal	45.8	1.8	4.9	3.8	2.2	6.2	4.9
Outer Superior	42.9	2.0	5.6	4.7	2.0	5.7	4.7
Outer SuperoTemporal	41.9	1.7	4.8	4.1	2.2	6.3	5.3
Outer Temporal	43.8	2.8	7.9	6.4	3.0	8.4	6.8
Outer InferoTemporal	46.0	3.0	8.5	6.6	3.5	9.9	7.7
Outer Inferior	46.0	2.6	7.2	5.6	4.7	13.2	10.3
Outer InferoNasal	46.5	2.4	6.7	5.1	3.3	9.4	7.2

All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.
Mean = Intercept of the ANOVA model
Repeatability SD = Square root of the residual variance.
Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance.
Repeatability limit = 2.8 x Repeatability SD.
Reproducibility limit = 2.8 x Reproducibility SD.
Repeatability CV% = (Repeatability SD)/Mean x 100%.
Reproducibility CV% = (Reproducibility SD)/Mean x 100%.

Table 3
Results of Deming Regression Analysis Stratified by Sector and Study Group

Sector	Group	Intercept (SE) µm	Int [95% CI] µm	Slope (SE) no units	Slope [95% CI] no units
Sector_01	Normal	4.69 (4.25)	[-3.65, 13.02]	0.88 (0.08)	[0.71, 1.04]
	Pathology	-2.46 (1.98)	[-6.35, 1.43]	1.03 (0.04)	[0.95, 1.10]
Sector_02	Normal	-9.71 (3.47)	[-16.52, -2.90]	1.16 (0.07)	[1.02, 1.29]
	Pathology	1.09 (1.16)	[-1.18, 3.35]	0.94 (0.02)	[0.90, 0.99]
Sector_03	Normal	-3.13 (2.95)	[-8.91, 2.65]	1.02 (0.06)	[0.91, 1.13]
	Pathology	-2.87 (1.45)	[-5.70, -0.03]	1.01 (0.03)	[0.95, 1.06]
Sector_04	Normal	-11.09 (4.48)	[-19.87, -2.31]	1.18 (0.09)	[1.01, 1.35]
	Pathology	-1.52 (1.28)	[-4.02, 0.99]	0.99 (0.02)	[0.94, 1.04]
Sector_05	Normal	-5.11 (3.33)	[-11.64, 1.42]	1.05 (0.06)	[0.93, 1.18]
	Pathology	-2.91 (1.21)	[-5.28, -0.55]	1.01 (0.02)	[0.97, 1.06]
Sector_06	Normal	2.65 (3.00)	[-3.23, 8.54]	0.90 (0.06)	[0.79, 1.02]
	Pathology	-2.26 (1.71)	[-5.61, 1.10]	1.00 (0.03)	[0.94, 1.07]
Sector_07	Normal	0.18 (3.23)	[-6.15, 6.51]	0.96 (0.06)	[0.84, 1.09]
	Pathology	-0.27 (1.03)	[-2.30, 1.76]	0.96 (0.02)	[0.92, 1.00]
Sector_08	Normal	3.79 (3.35)	[-2.78, 10.35]	0.89 (0.07)	[0.76, 1.02]
	Pathology	-16.11 (3.49)	[-22.95, -9.26]	1.30 (0.07)	[1.16, 1.43]
Sector_09	Normal	-1.51 (3.04)	[-7.47, 4.45]	0.98 (0.06)	[0.87, 1.10]
	Pathology	-7.65 (2.67)	[-12.89, -2.41]	1.12 (0.05)	[1.02, 1.23]
Sector_10	Normal	1.34 (3.77)	[-6.06, 8.73]	0.92 (0.08)	[0.77, 1.08]
	Pathology	-6.39 (1.53)	[-9.38, -3.40]	1.07 (0.03)	[1.01, 1.13]
Sector_11	Normal	-27.06 (5.06)	[-36.98, -17.13]	1.47 (0.10)	[1.27, 1.66]
	Pathology	-4.73 (1.60)	[-7.86, -1.60]	1.05 (0.03)	[0.98, 1.11]
Sector_12	Normal	-12.70 (4.37)	[-21.26, -4.14]	1.19 (0.08)	[1.03, 1.36]
	Pathology	-1.75 (2.00)	[-5.68, 2.18]	0.98 (0.04)	[0.90, 1.06]
Sector_13	Normal	-11.56 (4.80)	[-20.96, -2.15]	1.17 (0.09)	[0.99, 1.36]
	Pathology	1.11 (1.12)	[-1.08, 3.31]	0.93 (0.02)	[0.88, 0.97]
Sector_14	Normal	-6.34 (3.56)	[-13.31, 0.64]	1.08 (0.07)	[0.94, 1.22]
	Pathology	-8.46 (1.92)	[-12.21, -4.70]	1.11 (0.04)	[1.04, 1.18]
Sector_15	Normal	3.42 (3.57)	[-3.57, 10.41]	0.87 (0.07)	[0.73, 1.02]
	Pathology	-0.60 (1.10)	[-2.75, 1.55]	0.96 (0.02)	[0.92, 1.00]
Sector_16	Normal	-3.43 (2.88)	[-9.08, 2.22]	1.02 (0.06)	[0.91, 1.14]
	Pathology	-9.25 (2.99)	[-15.10, -3.39]	1.14 (0.06)	[1.02, 1.26]
Sector_17	Normal	-2.52 (3.10)	[-8.60, 3.55]	1.00 (0.06)	[0.88, 1.12]
	Pathology	-8.33 (2.67)	[-13.57, -3.09]	1.12 (0.05)	[1.02, 1.22]
Sector_18	Normal	-12.47 (3.22)	[-18.79, -6.15]	1.22 (0.07)	[1.09, 1.35]

Sector	Group	Intercept (SE) µm	Int [95% CI] µm	Slope (SE) no units	Slope [95% CI] no units
	Pathology	4.44 (1.43)	[1.65, 7.24]	0.86 (0.03)	[0.81, 0.92]
Sector_19	Normal	3.18 (4.83)	[-6.30, 12.65]	0.90 (0.10)	[0.71, 1.09]
	Pathology	-2.91 (3.80)	[-10.37, 4.54]	1.02 (0.08)	[0.87, 1.17]
Sector_20	Normal	-5.80 (4.60)	[-14.82, 3.22]	1.07 (0.09)	[0.89, 1.25]
	Pathology	-1.25 (3.07)	[-7.27, 4.77]	0.98 (0.06)	[0.86, 1.11]
Sector_21	Normal	-10.72 (7.16)	[-24.75, 3.31]	1.17 (0.14)	[0.88, 1.45]
	Pathology	-1.05 (2.20)	[-5.37, 3.26]	1.00 (0.05)	[0.91, 1.09]
Sector_22	Normal	-1.92 (2.59)	[-6.99, 3.15]	1.00 (0.05)	[0.90, 1.10]
	Pathology	-2.11 (2.38)	[-6.76, 2.55]	1.00 (0.05)	[0.90, 1.09]
Sector_23	Normal	-6.47 (3.10)	[-12.55, -0.39]	1.07 (0.07)	[0.95, 1.20]
	Pathology	3.59 (1.32)	[1.00, 6.18]	0.87 (0.03)	[0.81, 0.93]
Sector_24	Normal	-5.77 (2.51)	[-10.70, -0.85]	1.06 (0.06)	[0.95, 1.17]
	Pathology	-0.27 (1.86)	[-3.91, 3.37]	0.96 (0.04)	[0.88, 1.04]
Sector_25	Normal	-4.91 (3.25)	[-11.27, 1.45]	1.07 (0.07)	[0.94, 1.20]
	Pathology	1.91 (1.65)	[-1.32, 5.14]	0.92 (0.03)	[0.85, 0.99]
All Combined	Normal	-5.92 (0.61)	[-7.11, -4.73]	1.07 (0.01)	[1.05, 1.10]
All Combined	Pathology	-2.54 (0.36)	[-3.25, -1.83]	1.01 (0.01)	[0.99, 1.02]
All Combined	All Combined	-3.25 (0.30)	[-3.83, -2.66]	1.02 (0.01)	[1.01, 1.03]

Table 4
Bland Altman Limits of Agreement stratified by Sector and Study Group

Sector	Group	Mean Difference (SD) µm	Difference [min,max] µm	Limit of Agreement (lower) Estimate (SE) [95% CI] µm	Limit of Agreement (upper) Estimate (SE) [95% CI] µm
Sector_01	Normal	-1.59 (1.77)	[-7.4, 2.8]	-5.05 (0.24), [-5.5, -4.6]	1.88 (0.24), [1.4, 2.3]
	Pathology	-1.17 (2.98)	[-7.8, 14.7]	-7.00 (0.38), [-7.8, -6.3]	4.67 (0.38), [3.9, 5.4]
Sector_02	Normal	-1.83 (1.62)	[-5.9, 2.2]	-5.00 (0.22), [-5.4, -4.6]	1.33 (0.22), [0.9, 1.8]
	Pathology	-1.86 (2.15)	[-6.9, 11.6]	-6.08 (0.27), [-6.6, -5.5]	2.36 (0.27), [1.8, 2.9]
Sector_03	Normal	-1.94 (1.71)	[-6.5, 1.9]	-5.29 (0.23), [-5.7, -4.8]	1.41 (0.23), [1.0, 1.9]
	Pathology	-2.48 (2.23)	[-8.1, 5.2]	-6.84 (0.28), [-7.4, -6.3]	1.89 (0.28), [1.3, 2.4]
Sector_04	Normal	-1.70 (1.94)	[-7.3, 2.3]	-5.50 (0.26), [-6.0, -5.0]	2.09 (0.26), [1.6, 2.6]
	Pathology	-1.93 (1.96)	[-8.2, 2.0]	-5.77 (0.25), [-6.3, -5.3]	1.90 (0.25), [1.4, 2.4]
Sector_05	Normal	-2.49 (1.79)	[-7.1, 1.4]	-6.00 (0.24), [-6.5, -5.5]	1.03 (0.24), [0.6, 1.5]
	Pathology	-2.24 (1.83)	[-7.5, 2.9]	-5.83 (0.23), [-6.3, -5.4]	1.34 (0.23), [0.9, 1.8]
Sector_06	Normal	-2.45 (1.81)	[-7.7, 2.0]	-6.00 (0.24), [-6.5, -5.5]	1.11 (0.24), [0.6, 1.6]
	Pathology	-2.04 (2.21)	[-7.1, 6.4]	-6.37 (0.28), [-6.9, -5.8]	2.30 (0.28), [1.7, 2.9]
Sector_07	Normal	-1.64 (1.75)	[-6.3, 3.1]	-5.07 (0.23), [-5.5, -4.6]	1.79 (0.23), [1.3, 2.3]
	Pathology	-2.46 (1.78)	[-6.9, 2.5]	-5.94 (0.23), [-6.4, -5.5]	1.03 (0.23), [0.6, 1.5]
Sector_08	Normal	-1.80 (1.81)	[-6.3, 1.8]	-5.34 (0.24), [-5.8, -4.9]	1.75 (0.24), [1.3, 2.2]
	Pathology	-1.22 (3.55)	[-6.4, 17.1]	-8.19 (0.45), [-9.1, -7.3]	5.75 (0.45), [4.9, 6.6]
Sector_09	Normal	-2.29 (1.80)	[-7.8, 1.8]	-5.81 (0.24), [-6.3, -5.3]	1.23 (0.24), [0.8, 1.7]
	Pathology	-1.50 (3.40)	[-6.9, 14.7]	-8.16 (0.43), [-9.0, -7.3]	5.16 (0.43), [4.3, 6.0]

Sector	Group	Mean Difference (SD) µm	Difference [min,max] µm	Limit of Agreement (lower) Estimate (SE) [95% CI] µm	Limit of Agreement (upper) Estimate (SE) [95% CI] µm
Sector_10	Normal	-2.38 (2.28)	[-9.8, 2.7]	-6.86 (0.31), [-7.5, -6.3]	2.09 (0.31), [1.5, 2.7]
	Pathology	-2.94 (2.36)	[-9.4, 3.6]	-7.58 (0.31), [-8.2, -7.0]	1.69 (0.31), [1.1, 2.3]
Sector_11	Normal	-3.10 (2.80)	[-15.7, 3.8]	-8.58 (0.39), [-9.3, -7.8]	2.38 (0.39), [1.6, 3.1]
	Pathology	-2.42 (2.38)	[-9.1, 6.7]	-7.08 (0.32), [-7.7, -6.4]	2.24 (0.32), [1.6, 2.9]
Sector_12	Normal	-2.73 (2.59)	[-10.1, 4.0]	-7.80 (0.35), [-8.5, -7.1]	2.34 (0.35), [1.7, 3.0]
	Pathology	-2.72 (2.61)	[-9.2, 8.2]	-7.84 (0.36), [-8.6, -7.1]	2.40 (0.36), [1.7, 3.1]
Sector_13	Normal	-2.70 (2.53)	[-12.3, 4.2]	-7.66 (0.34), [-8.3, -7.0]	2.25 (0.34), [1.6, 2.9]
	Pathology	-2.65 (2.01)	[-7.8, 1.8]	-6.59 (0.27), [-7.1, -6.1]	1.30 (0.27), [0.8, 1.8]
Sector_14	Normal	-2.52 (2.54)	[-7.9, 3.0]	-7.50 (0.34), [-8.2, -6.8]	2.46 (0.34), [1.8, 3.1]
	Pathology	-2.92 (2.68)	[-11.1, 7.2]	-8.17 (0.34), [-8.8, -7.5]	2.34 (0.34), [1.7, 3.0]
Sector_15	Normal	-2.70 (2.33)	[-8.8, 2.6]	-7.26 (0.31), [-7.9, -6.6]	1.86 (0.31), [1.2, 2.5]
	Pathology	-2.50 (2.20)	[-8.7, 3.3]	-6.81 (0.28), [-7.4, -6.3]	1.81 (0.28), [1.3, 2.4]
Sector_16	Normal	-2.26 (1.92)	[-8.3, 1.4]	-6.02 (0.26), [-6.5, -5.5]	1.50 (0.26), [1.0, 2.0]
	Pathology	-2.65 (3.76)	[-8.9, 14.0]	-10.02 (0.48), [-11.0, -9.1]	4.72 (0.48), [3.8, 5.7]
Sector_17	Normal	-2.53 (2.34)	[-9.4, 5.8]	-7.12 (0.31), [-7.7, -6.5]	2.06 (0.31), [1.4, 2.7]
	Pathology	-2.35 (3.59)	[-15.5, 14.7]	-9.39 (0.46), [-10.3, -8.5]	4.69 (0.46), [3.8, 5.6]
Sector_18	Normal	-2.10 (2.29)	[-8.3, 4.6]	-6.58 (0.33), [-7.2, -5.9]	2.39 (0.33), [1.7, 3.1]
	Pathology	-2.09 (2.72)	[-16.7, 4.1]	-7.42 (0.40), [-8.2, -6.6]	3.24 (0.40), [2.4, 4.0]
Sector_19	Normal	-1.87 (2.01)	[-6.1, 3.5]	-5.82 (0.37), [-6.5, -5.1]	2.08 (0.37), [1.3, 2.8]

Sector	Group	Mean Difference (SD) µm	Difference [min,max] µm	Limit of Agreement (lower) Estimate (SE) [95% CI] µm	Limit of Agreement (upper) Estimate (SE) [95% CI] µm
	Pathology	-2.00 (3.86)	[-18.0, 5.7]	-9.56 (0.66), [-10.9, -8.3]	5.56 (0.66), [4.3, 6.9]
Sector_20	Normal	-2.31 (2.59)	[-9.0, 4.0]	-7.38 (0.45), [-8.3, -6.5]	2.77 (0.45), [1.9, 3.7]
	Pathology	-2.01 (3.45)	[-15.5, 7.0]	-8.77 (0.65), [-10.1, -7.5]	4.74 (0.65), [3.5, 6.0]
Sector_21	Normal	-2.55 (2.84)	[-13.6, 5.9]	-8.12 (0.44), [-9.0, -7.3]	3.02 (0.44), [2.2, 3.9]
	Pathology	-1.10 (2.74)	[-7.0, 5.5]	-6.47 (0.47), [-7.4, -5.5]	4.27 (0.47), [3.3, 5.2]
Sector_22	Normal	-1.91 (2.28)	[-8.2, 3.8]	-6.38 (0.34), [-7.0, -5.7]	2.56 (0.34), [1.9, 3.2]
	Pathology	-2.26 (3.68)	[-14.1, 8.3]	-9.48 (0.53), [-10.5, -8.4]	4.96 (0.53), [3.9, 6.0]
Sector_23	Normal	-2.93 (2.22)	[-10.0, 3.9]	-7.27 (0.31), [-7.9, -6.7]	1.41 (0.31), [0.8, 2.0]
	Pathology	-2.19 (2.35)	[-7.4, 4.2]	-6.80 (0.32), [-7.4, -6.2]	2.41 (0.32), [1.8, 3.0]
Sector_24	Normal	-3.04 (2.20)	[-9.3, 2.7]	-7.34 (0.34), [-8.0, -6.7]	1.26 (0.34), [0.6, 1.9]
	Pathology	-2.24 (2.38)	[-8.3, 8.4]	-6.91 (0.34), [-7.6, -6.2]	2.44 (0.34), [1.8, 3.1]
Sector_25	Normal	-1.67 (2.36)	[-7.6, 4.5]	-6.30 (0.35), [-7.0, -5.6]	2.96 (0.35), [2.3, 3.6]
	Pathology	-1.74 (2.61)	[-9.6, 4.3]	-6.87 (0.36), [-7.6, -6.2]	3.38 (0.36), [2.7, 4.1]
All Combined	Normal	-2.28 (2.21)	[-15.7, 5.9]	-6.62 (0.06), [-6.7, -6.5]	2.06 (0.06), [1.9, 2.2]
All Combined	Pathology	-2.17 (2.77)	[-18.0, 17.1]	-7.60 (0.07), [-7.7, -7.4]	3.26 (0.07), [3.1, 3.4]
All Combined	All Combined	-2.22 (2.52)	[-18.0, 17.1]	-7.15 (0.05), [-7.2, -7.1]	2.71 (0.05), [2.6, 2.8]

SUMMARY (21 CFR §807.92(b)(3))

As described in this 510(k) Summary, all testing deemed necessary was conducted on the CIRRUS HD-OCT with Software Version 10 to ensure that the device is substantially equivalent to the predicate device for its intended use when used in accordance with its Instructions for Use.