JAN 19 2012

SECTION 5. 510(K) SUMMARY

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510(k) SUMMARY
(per 21 CFR §807.92)

Cirrus HD-OCT with Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head and Ganglion Cell Normative Databases

GENERAL INFORMATION

Manufacturer:	Carl Zeiss Meditec Inc. 5160 Hacienda Drive Dublin, California 94568 (925) 557-4616 (phone) (925) 557-4259 (fax) Est. Reg. No. 2918630
Contact Person:	Judith A. Brimacombe, MA Director, Regulatory/Clinical Affairs Carl Zeiss Meditec Inc. 5160 Hacienda Drive Dublin, California 94568 (925) 557-4616 (phone) (925) 557-4259 (fax)
Date Summary Prepared:	January 19, 2012
Classification Name:	Tomography, Optical Coherence; Ophthalmoscope
Classification:	Class II (acc. 21 CFR 886.1570)
Product Code:	OBO
Trade/Proprietary Name:	Cirrus HD-OCT with Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head and Ganglion Cell Normative Databases
Models:	400 and 4000

PREDICATE DEVICE

Company:	Carl Zeiss Meditec, Inc.
Device:	Cirrus™ HD-OCT (K083291)

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Company:	Heidelberg Engineering, Inc.
Device:	Spectralis™ HRA+OCT (K101223)
Company:	Optovue, Inc.
Device:	RTVue with Normative Database (K101505)

INTENDED USE

The Cirrus™ HD-OCT with Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head and Ganglion Cell Normative Databases is indicated for in-vivo viewing, axial cross-sectional, and three-dimensional imaging and measurement of anterior and posterior ocular structures.

INDICATIONS FOR USE

The Cirrus™ HD-OCT is a non-contact, high resolution tomographic and biomicroscopic imaging device. It is indicated for in-vivo viewing, axial cross-sectional, and three-dimensional imaging and measurement of anterior and posterior ocular structures, including cornea, retina, retinal nerve fiber layer, ganglion cell plus inner plexiform layer, macula, and optic nerve head. The Cirrus normative databases are quantitative tools 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. The Cirrus HD-OCT is intended for use as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, macular holes, cystoid macular edema, diabetic retinopathy, age-related macular degeneration, and glaucoma.

DEVICE DESCRIPTION

The Cirrus™ HD-OCT is a computerized instrument that acquires and analyzes 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 4000 and Model 400. In the Cirrus HD-OCT Model 4000 instrument, the fundus camera is a line scanning ophthalmoscope. The Cirrus HD-OCT Model 400 is similar to the Model 4000 except that it provides the fundus image using the OCT scanner only.

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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.

Visit-to-visit comparison of images and measurements is available for the macula. Specifically, change in macular thickness, area and volume of Retinal Pigment Epithelium (RPE) elevations, area of sub-RPE illumination and distance of Sub-RPE illumination to the fovea. Change analysis of multiple visits, up to eight, can be performed for RNFL thickness, neuroretinal rim area, average and vertical cup-to-disc area ratio, cup volume, and macular thickness.

Advanced RPE Measurements

The Advanced RPE Analysis allows the user to examine the status of the RPE in greater detail than the Macular Thickness Analysis. In particular, Cirrus provides two algorithms, one to identify and measure areas of sub-RPE illumination where the OCT is able to penetrate through to the choroid, indicating that the RPE is atrophic (often associated with geographic atrophy), and one to identify and measure elevations in the RPE (often associated with drusen).

Ganglion Cell Analysis Measurements

The Ganglion Cell Analysis (GCA) measures the thickness of the sum of the ganglion cell layer and inner plexiform layer (GCL + IPL) using data from the Macular 200 x 200 or Macular 512 x 128 cube scan patterns.

Guided Progression Analysis (GPA)

GPA compares measurements from the Optic Disc cube 200 x 200 scan over time and determines if change over time has occurred that exceeds the test-retest variability. The analysis includes a chronological display of RNFL thickness maps, RNFL change maps, cup and disc boundaries, and thickness graphs representing rate of change for average thickness parameters and average cup-to-disc ratio as well as RNFL thickness profiles comparing the current exam to the baseline exams.

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SUBSTANTIAL EQUIVALENCE

It is the opinion of Carl Zeiss Meditec, Incorporated that the Cirrus HD-OCT with Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head and Ganglion Cell Normative Databases is substantially equivalent to the Cirrus HD-OCT with Retinal Nerve Fiber Layer (RNFL) and Macular Normative Databases, the Heidelberg Engineering Spectralis™ HRA+OCT and the Optovue RTVue®. The indications for use for the Cirrus HD-OCT with Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head and Ganglion Cell Normative Databases is similar to the indications for the predicate devices cited in this application. A technological comparison and clinical testing demonstrate that the Cirrus HD-OCT with Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head and Ganglion Cell Normative Databases is functionally equivalent to the predicate devices.

Evaluation performed on the Cirrus HD-OCT with Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head and Ganglion Cell Normative Databases supports the expanded 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.

CLINICAL EVALUATION

Clinical data were collected and evaluated to support the indications for use statement for the Cirrus HD-OCT with Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head and Ganglion Cell Normative Databases and to demonstrate substantial equivalence to the Cirrus HD-OCT with RNFL and Macular Normative Databases and to the Spectralis™ HRA+OCT. These studies are summarized below.

Advanced RPE Analysis Study: Measurements of Area of Increased Illumination Under the RPE

To evaluate the Cirrus HD-OCT's method of measuring areas of sub-RPE illumination, a non-significant risk clinical study was conducted to compare the Cirrus HD-OCT automated measurements of the illumination area under the retinal pigment epithelium (RPE) to expert manual measurements of areas of hypofluorescence typical of geographic atrophy in fundus autofluorescence (FAF) images taken with the Spectralis HRA+OCT (Spectralis Heidelberg Retina Angiograph (HRA) and Spectralis OCT). Only subjects that were being evaluated for dry AMD with geographic atrophy and who were scheduled for FAF imaging were recruited into the study.

Four sites participated in the clinical data collection. Fifty-two eyes from 52 subjects were included in the data analysis. The mean (SD) lesion size detected in the study was

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5.9 (4.5) mm^2 for FAF and 5.8 (4.0) mm^2 for OCT; the mean difference was 0.1 (1.9) mm^2. A paired t-test showed no significant difference between the measurements obtained by the two instruments. Regression analysis showed good correlation between FAF and OCT measurements with a slope of 0.81, an intercept of 1.05, and an R^2 of 0.82.

The differences between the two imaging modalities did not appear to affect the measurement outcomes. The results of the study showed that GA area measurements from expert manual segmentation of FAF images and the Cirrus HD-OCT automated algorithm were comparable.

Advanced RPE Analysis Study: Measurements of Elevated RPE

To evaluate the Cirrus HD-OCT's automated method of measuring elevated RPE, a non-significant risk clinical study was conducted to compare the areas designated as elevated retinal pigment epithelium (RPE) by an automated algorithm of the Cirrus HD-OCT to those manually drawn by experts designated as drusen on color fundus photographs (CFPs). Subjects were 50 years of age and older with a diagnosis of dry age-related macular degeneration (AMD) with macular drusen.

Three sites participated in the clinical data collection. Seventy eyes from 70 subjects were considered for inclusion in the data analysis. The results showed that there were significant differences between the two modalities that can be explained by the fundamental differences in the technology. Drusen maps from OCT data represented significant disruptions to the RPE geometry, while color fundus photos identified abnormalities in macular pigmentation. From this study, it can be concluded that these two modalities provide complementary information that is useful for evaluating patients with age-related macular degeneration.

Optic Nerve Head Normative Database

The Optic Nerve Head Analysis (ONH) Normative Database compares optic nerve head measurements in a population of normal subjects. It was derived from a post-hoc analysis of the 200 x 200 optic disc cube scans from 282 eyes of the 284 eyes included in the RNFL normative database referenced in a previous 510(k), K083291. The normative database is comprised of 282 subjects, aged 19-84 years. The data were collected from seven sites. The normative database has a fairly even gender distribution (133 males, 149 females). Ethnicity breakdown of the normative database is as follows: 43% Caucasians, 24% Asians, 18% African American, 12% Hispanic, 1% Indian, and 6% mixed ethnicity.

The optic nerve head parameters were found to depend on optic disc area and age. Therefore, both optic disc area-correction and age-correction were performed in generating the normal limits. The majority of disc areas were between 1.3 mm^2 and

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2.5 mm^2. As such, normal limits were not defined for eyes with disc sizes outside of this range. The optic disc parameters that may be compared include Rim Area, Average Cup-to-Disc Ratio, Vertical Cup-to-Disc Ratio, and Cup Volume.

Ganglion Cell Normative Database

The Cirrus Ganglion Cell normative database was derived from a post-hoc analysis of the Macula normative database referenced in a previous 510(k), K083291. To establish reference values, the scans acquired as part of the Cirrus HD-OCT Macular Thickness normative database were analyzed using a segmentation algorithm that identifies the thickness of the combined ganglion cell plus inner plexiform layers.

The database parameters are the same as those used in the original macula normative database. The Ganglion Cell Analysis database utilized the same 282 subjects, aged 19-84 years that were deemed representative of a normal population. The data was collected from seven sites. The normative database is age-corrected and has a gender distribution of 133 males, 149 females. Ethnicity breakdown of the normative database is as follows: 43% Caucasians, 24% Asians, 18% African American, 12% Hispanic, 1% Indian, and 6% mixed ethnicity.

Measurements of Area of Increased Illumination Under the RPE Repeatability and Reproducibility

A non-significant risk single-site clinical study was conducted wherein subjects identified to have dry AMD with geographic atrophy were examined on three Cirrus HD-OCT instruments by three operators. For the inter-device phase of the study, all three units were used and a single operator performed all scans. For the inter-operator phase of the study, three operators obtained scans and only the Cirrus HD-OCT Unit 1 was used.

A total number of 46 subjects were enrolled in Phase 1 study. There were 49 eyes of 37 subjects qualified for inclusion in the data analysis. A total number of 46 subjects were enrolled in Phase 2. There were 53 eyes of 39 subjects qualified for inclusion in the data analysis.

Tables 1 and 2 present the repeatability and the reproducibility standard deviation (SD) and limits of the sub-RPE illumination area measurements and the closest distance to the fovea by the automated algorithm for both 200 x 200 and 512 x 128 scans.

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Table 1. Repeatability and Reproducibility of Area of Sub-RPE Illumination Automated Algorithm

Scan	Repeatability		Reproducibility		
	Repeatability SD (mm^2)	Repeatability Limit[a] (mm^2)	Reproducibility SD (mm^2)	Reproducibility Limit[b] (mm^2)	CV[c]
200x200 Scan	0.8887	2.4885	0.9450	2.6460	12.5%
512x128 Scan	0.8683	2.4313	1.0317	2.8889	15.8%
a. Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 x Repeatability SD.					
b. Reproducibility Limit is the upper 95% limit calculated for the difference between results repeated with different operators on different instruments. Per ISO 5725-1 and ISO 5725-6, Reproducibility limit = 2.8 x Reproducibility SD.					
c. Coefficient of Variability is CV = SD divided by the mean.					

Table 2. Repeatability and Reproducibility of Closest Distance to Fovea Automated Algorithm

Scan	Repeatability		Reproducibility	
	Repeatability SD (mm)	Repeatability Limit[a] (mm)	Reproducibility SD (mm)	Reproducibility Limit[b] (mm)
200x200 Scan	0.0739	0.2070	0.0762	0.2133
512x128 Scan	0.1247	0.3492	0.1257	0.3520
a. Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 x Repeatability SD.				
b. Reproducibility Limit is the upper 95% limit calculated for the difference between results repeated with different operators on different instruments. Per ISO 5725-1 and ISO 5725-6, Reproducibility limit = 2.8 x Reproducibility SD.				

Tables 3 and 4 present the repeatability and the reproducibility standard deviation (SD) and limits of the sub-RPE illumination area measurements and the closest distance to the fovea after manual editing for the 200 x 200 scans. There was a significant improvement in all the repeatability and reproducibility values when manual editing was performed.

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Table 3. Repeatability and Reproducibility of Area of Sub-RPE Illumination Manually Edited

Scan	Repeatability		Reproducibility		
	Repeatability SD (mm^2)	Repeatability Limit[a] (mm^2)	Reproducibility SD (mm^2)	Reproducibility Limit[b] (mm^2)	CV[c]
200x200 Scan	0.2273	0.6365	0.3823	1.0705	4.3%
a. Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 x Repeatability SD.					
b. Reproducibility Limit is the upper 95% limit calculated for the difference between results repeated with different operators on different instruments. Per ISO 5725-1 and ISO 5725-6, Reproducibility limit = 2.8 x Reproducibility SD.					
c. Coefficient of Variability is CV = SD divided by the mean.					

Table 4. Repeatability and Reproducibility of Closest Distance to Fovea Manually Edited

Scan	Repeatability		Reproducibility	
	Repeatability SD (mm)	Repeatability Limit[a] (mm)	Reproducibility SD (mm)	Reproducibility Limit[b] (mm)
200x200 Scan	0.0354	0.0990	0.0439	0.1229
a. Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 x Repeatability SD.				
b. Reproducibility Limit is the upper 95% limit calculated for the difference between results repeated with different operators on different instruments. Per ISO 5725-1 and ISO 5725-6, Reproducibility limit = 2.8 x Reproducibility SD.				

Measurements of Elevated RPE Repeatability and Reproducibility

A non-significant risk single-site clinical study was conducted wherein subjects identified to have dry AMD with macular drusen were examined on three Cirrus HD-OCT instruments by three operators. For the inter-device phase of the study, all three units were used and a single operator performed all scans. For the inter-operator phase of the study, three operators obtained scans and only the Cirrus HD-OCT Unit 1 was used.

A total number of 39 subjects were enrolled in Phase 1 study. There were 26 eyes of 23 subjects qualified for inclusion in the data analysis. A total number of 39 subjects were enrolled in Phase 2. There were 24 eyes of 21 subjects qualified for inclusion in the data analysis.

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Tables 5 and 6 present the repeatability and the reproducibility standard deviation (SD) and limits of the area (Table 5) and volume (Table 6) of the RPE elevations by the automated algorithm for both 200 x 200 and 512 x 128 scans within the 3 and 5 mm circles.

Table 5. Repeatability and Reproducibility of Area of RPE Elevations

Circle	Repeatability		Reproducibility		
	Repeatability SD (mm^2)	Repeatability Limit[a] (mm^2)	Reproducibility SD (mm^2)	Reproducibility Limit[b] (mm^2)	CV[c]
200x200 Scan					
3 mm Circle	0.1295	0.3626	0.1568	0.4389	10.1%
5 mm Circle	0.1012	0.2834	0.1455	0.4073	4.9%
512x128 Scan					
3 mm Circle	0.0837	0.2343	0.0998	0.2794	7.5%
5 mm Circle	0.1537	0.4304	0.1936	0.5422	9.6%
a. Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 x Repeatability SD.					
b. Reproducibility Limit is the upper 95% limit calculated for the difference between results repeated with different operators on different instruments Per ISO 5725-1 and ISO 5725-6, Reproducibility limit = 2.8 x Reproducibility SD.					
c. Coefficient of Variability is CV = SD divided by the mean.					

Table 6. Repeatability and Reproducibility of Volume of RPE Elevations

Circle	Repeatability		Reproducibility		
	Repeatability SD (mm^2)	Repeatability Limit[a] (mm^2)	Reproducibility SD (mm^2)	Reproducibility Limit[b] (mm^2)	CV[c]
200x200 Scan					
3 mm Circle	0.0117	0.0327	0.0122	0.0341	15.2%
5 mm Circle	0.0098	0.0275	0.0106	0.0298	8.3%
512x128 Scan					
3 mm Circle	0.0074	0.0206	0.0084	0.0235	12.0%
5 mm Circle	0.0088	0.0245	0.0103	0.0288	11.4%
a. Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 x Repeatability SD.					
b. Reproducibility Limit is the upper 95% limit calculated for the difference between results repeated with different operators on different instruments. Per ISO 5725-1 and ISO 5725-6, Reproducibility limit = 2.8 x Reproducibility SD.					
c. Coefficient of Variability is CV = SD divided by the mean.					

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Optic Nerve Head and Ganglion Cell Analysis Repeatability and Reproducibility

A non-significant risk clinical study was conducted with 63 normal subjects to determine the inter-operator and inter-device repeatability of Cirrus optic nerve head parameters. The study was performed in two phases. Phase 1 was inter-operator testing, wherein four operators acquired measurements on one Cirrus HD-OCT unit. Phase 2 was inter-device testing, wherein one operator acquired measurements on four Cirrus HD-OCT units. The repeatability and reproducibility standard deviation (SD) and limits for the ONH and GCA parameters are shown in Table 7.

Table 7. Cirrus Repeatability and Reproducibility of GCA and ONH Parameters – Normal Subjects

	Repeatability		Reproducibility		
	Repeatability SD	**Repeatability Limit[a]**	**Reproducibility SD**	**Reproducibility Limit[b]**	**CV[c]**
GCA Parameters					
Average Thickness (μm)	0.5839	1.6348	0.7479	2.0942	0.7%
Minimum Thickness (μm)	2.8630	8.0165	2.8935	8.1018	2.5%
Temporal-Superior Thickness (μm)	0.8394	2.3502	0.9496	2.6590	1.0%
Superior Thickness (μm)	0.9115	2.5522	1.0723	3.0024	1.1%
Nasal-Superior Thickness (μm)	0.9198	2.5753	1.0412	2.9154	1.0%
Nasal-Inferior Thickness (μm)	1.6735	4.6857	1.7330	4.8525	1.5%
Inferior Thickness (μm)	0.9962	2.7894	1.1907	3.3339	1.2%
Temporal-Inferior Thickness (μm)	0.8196	2.2948	0.9177	2.5696	1.0%
ONH Parameters					
Cup Disc Ratio	0.0136	0.0380	0.0242	0.0679	5.4%
Vertical CD Ratio	0.0243	0.0681	0.0302	0.0846	7.1%
Disc Area (mm^2)	0.0538	0.1506	0.0942	0.2637	5.4%
Rim Area (mm^2)	0.0420	0.1177	0.0619	0.1733	4.7%
Cup Volume (mm^3)	0.0065	0.0181	0.0102	0.0287	7.8%
a. Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 x Repeatability SD.					
b. Reproducibility Limit is the upper 95% limit calculated for the difference between results repeated with different operators on different instruments. Per ISO 5725-1 and ISO 5725-6, Reproducibility limit = 2.8 x Reproducibility SD.					
c. Coefficient of Variability is CV = SD divided by the mean.					

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A clinical study[1] was conducted with 55 glaucomatous subjects to determine the intra-visit and inter-visit repeatability of Cirrus HD-OCT optic nerve head parameters. The study was performed in two phases. Phase 1 of the study was designed to determine intra-visit variability, wherein each subject was imaged three times during a single visit on one Cirrus HD-OCT by one operator. Phase 2 was designed to determine inter-visit variability, wherein each subject was imaged on four subsequent visits by one operator.

The study subjects ranged in age from 46 to 87 years; the mean was 70.7 ± 11.1 years. The glaucomatous subjects were comprised of 26 mild, 11 moderate, and 18 severe cases. The repeatability and visit-to-visit variability standard deviation (SD) and limits for the ONH parameters are shown in Table 8.

Table 8. Repeatability and Visit-to-Visit Variability of ONH Parameters – Glaucomatous Subjects

	Repeatability SD	Repeatability Limit[(a)]	Visit-to-Visit Variability SD	Visit-to-Visit Variability Limit[(b)]	CV%[(c)]
Disc Area	0.084 mm^2	0.233 mm^2	0.084 mm^2	0.233 mm^2	4.4%
Rim Area	0.045 mm^2	0.125 mm^2	0.045 mm^2	0.125 mm^2	6.6%
Average Cup-to-Disc Ratio	0.009	0.025	0.009	0.025	1.2%
Vertical Cup-to-Disc Ratio	0.014	0.039	0.015	0.042	1.9%
Cup Volume	0.032 mm^3	0.089 mm^3	0.063 mm^3	0.175 mm^3	11.7%
(a) Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 x Repeatability SD.					
(b) Visit to Visit Variability Limit is the upper 95% limit for the difference between repeated results over multiple visits. Per ISO 5725-1 and ISO 5725-6, Visit to Visit Variability Limit = 2.8 x Visit to Visit SD.					
(c) Coefficient of Variability is CV = SD divided by the mean.					
Note: Operator and device variability were not considered for this study.					

1 Derived from Mwanza, JC, Chang, RT, Budenz, DL, Durbin, MK, Gendy, MG, Shi, W, Feuer WJ. Reproducibility of Peripapillary Retinal Nerve Fiber Layer Thickness and Optic Nerve Head Parameters Measured with Cirrus HD-OCT in Glaucomatous Eyes. IOVS 2010; 51:5724-5730.

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A total of 119 subjects with glaucoma were enrolled in a clinical study conducted at four sites. Ninety-four subjects with two qualified scans each were included in the analysis, of which 45 were categorized as mild glaucoma, 20 as moderate glaucoma and 19 as severe glaucoma. The mean age of the included subjects was 66.9 years, with a range from 43 to 89 years. The repeatability SD and limits for the GCA parameters are shown in Table 9.

Table 9. Repeatability of GCA Parameters - Glaucomatous Subjects

GCA Parameters (µm)	Repeatability		
	Repeatability SD	Repeatability Limit[a]	CV[b] %
Overall			
Average GCL + IPL Thickness	0.6274	1.7567	1.0%
Minimum GCL + IPL Thickness	1.5246	4.2689	2.6%
Temporal-Superior GCL + IPL Thickness	1.2204	3.4171	1.8%
Superior GCL + IPL Thickness	1.2653	3.5429	1.8%
Nasal-Superior GCL + IPL Thickness	0.8219	2.3013	1.2%
Nasal-Inferior GCL + IPL Thickness	1.1204	3.1371	1.7%
Inferior GCL + IPL Thickness	1.0569	2.9593	1.7%
Temporal-Inferior GCL + IPL Thickness	1.2160	3.4049	2.0%
Mild Glaucoma			
Average GCL + IPL Thickness	0.5099	1.4277	0.7%
Minimum GCL + IPL Thickness	0.9000	2.5200	1.4%
Temporal-Superior GCL + IPL Thickness	0.8062	2.2574	1.2%
Superior GCL + IPL Thickness	1.0198	2.8555	1.4%
Nasal-Superior GCL + IPL Thickness	0.8367	2.3426	1.1%
Nasal-Inferior GCL + IPL Thickness	1.1489	3.2170	1.6%
Inferior GCL + IPL Thickness	1.0677	2.9896	1.6%
Temporal-Inferior GCL + IPL Thickness	1.0488	2.9367	1.6%
Moderate Glaucoma			
Average GCL + IPL Thickness	0.7661	2.1452	1.2%
Minimum GCL + IPL Thickness	1.1132	3.1169	2.1%
Temporal-Superior GCL + IPL Thickness	1.3433	3.7611	2.1%
Superior GCL + IPL Thickness	1.8238	5.1065	2.9%
Nasal-Superior GCL + IPL Thickness	0.8209	2.2986	1.2%
Nasal-Inferior GCL + IPL Thickness	0.8341	2.3354	1.4%
Inferior GCL + IPL Thickness	1.1325	3.1711	2.0%
Temporal-Inferior GCL + IPL Thickness	0.8723	2.4424	1.5%
Severe Glaucoma			
Average GCL + IPL Thickness	0.7071	1.9799	1.2%
Minimum GCL + IPL Thickness	2.6682	7.4708	5.3%
Temporal-Superior GCL + IPL Thickness	1.7728	4.9639	2.9%
Superior GCL + IPL Thickness	1.0235	2.8659	1.6%
Nasal-Superior GCL + IPL Thickness	0.7868	2.2030	1.2%
Nasal-Inferior GCL + IPL Thickness	1.3093	3.6661	2.1%
Inferior GCL + IPL Thickness	0.9386	2.6281	1.6%
Temporal-Inferior GCL + IPL Thickness	1.7795	4.9826	3.3%

a. Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 x Repeatability SD.

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b. Coefficient of Variability is CV = SD divided by the mean.

SUMMARY

As described in this 510(k) Summary, all testing deemed necessary was conducted on the Cirrus HD-OCT with Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head and Ganglion Cell Normative Databases to ensure that the device is safe and effective for its intended use when used in accordance with its Instructions for Use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 19 2012

Carl Zeiss Meditec, Inc.
c/o Ms. Judith A. Brimacombe, M.A.
Director, Clinical/Regulatory Affairs
5160 Hacienda Drive
Dublin, CA 94568

Re: K111157
Trade/Device Name: Cirrus HD-OCT with Retinal Nerve Fiber Layer, Macular, Optic Nerve Head and Ganglion Cell Normative Databases; Model 4000 and 400
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO
Dated: December 9, 2011
Received: December 12, 2011

Dear Ms. Brimacombe:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Keosa Alexander

for

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

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K111157

Device Name: Cirrus HD-OCT with Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head, and Ganglion Cell Normative Databases

Models: 400 and 4000

Indications for Use:

The Cirrus™ HD-OCT is a non-contact, high resolution tomographic and biomicroscopic imaging device. It is indicated for in-vivo viewing, axial cross-sectional, and three-dimensional imaging and measurement of anterior and posterior ocular structures, including cornea, retina, retinal nerve fiber layer, ganglion cell plus inner plexiform layer, macula, and optic nerve head. The Cirrus normative databases are quantitative tools 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. The Cirrus HD-OCT is intended for use as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, macular holes, cystoid macular edema, diabetic retinopathy, age-related macular degeneration, and glaucoma.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K111157