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510(K) SUMMARY

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This 510(k) Summary information is being submitted in accordance with the requirements of 21 CFR 807.92(a).

SUBMITTER NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON, AND DATE SUMMARY PREPARED

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Summary Prepared:	June 14, 2012

NAME OF DEVICE, INCLUDING TRADE NAME AND CLASSIFICATION NAME

Trade/Proprietary Name:	CIRRUS photo Models 600 and 800
Common/Usual Name:	Optical Coherence Tomography Fundus Camera
Classification Name:	Tomography, Optical coherence Camera, Ophthalmic, AC-powered
Product Code and Class:	OBO – Class II HKI – Class II
Classification Number:	886.1570 886.1120

PREDICATE DEVICES

The CIRRUS photo (Models 600 and 800) is substantially equivalent to the Carl Zeiss Meditec VISUCAM PRO NM Digital Camera (K052268), the Carl Zeiss Meditec Cirrus HD-OCT Optical Coherence Tomographer with Retinal Nerve Fiber Layer (RNFL), Macular and Optic Nerve Head Normative Databases, Model 4000 (K083291; K111157), the Carl Zeiss Meditec FF450 plus Fundus Camera (K011877), the Topcon TRC-NW8F (K100207), and the Topcon 3D Optical Coherence Tomography 3D OCT-2000 (K092470).

The CIRRUS photo is substantially equivalent to these cleared devices with regard to indications for use and technological characteristics.

DEVICE DESCRIPTION

The CIRRUS photo is a non-contact, high resolution digital, tomographic and biomicroscopic imaging device that merges fundus imaging and optical coherence tomography into a single device. To optimize the workflow, the system applies the same beam delivery system for imaging and scanning.

INDICATIONS FOR USE

The CIRRUS photo is a non-contact, high resolution tomographic and biomicroscopic imaging device that incorporates a digital camera which is suitable for photographing, displaying and storing the data of the retina and surrounding parts of the eye to be examined under mydriatic and non-mydriatic conditions.

These photographs support the diagnosis and subsequent observation of eye diseases which can be visually monitored and photographically documented. The CIRRUS photo is indicated for *in vivo* viewing, axial cross sectional, and three-dimensional imaging and measurement of posterior ocular structures, including retina, retinal nerve fiber layer, macula, and optic disc as well as imaging of anterior ocular structures, including the cornea.

It also includes a Retinal Nerve Fiber Layer (RNFL), Optic Nerve Head (ONH), and Macular Normative Database which is a quantitative tool for the comparison of retinal nerve fiber layer, optic nerve head, and the macula in the human retina to a database of known normal subjects. It 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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The CIRRUS photo has very similar indications for use and operating characteristics as the predicate devices. The CIRRUS photo combines into a single system the functionalities and indications for use from each of the predicate devices.

The fundus camera unit of the CIRRUS photo utilizes the same imaging properties and technology as the cleared VISUCAM PRO NM Digital Camera to record morphologic images of the human retina under mydriatic and non-mydriatic conditions, respectively. The spectral domain optical coherence tomographer SD-OCT Module is the same optical coherence tomography system as in the cleared Cirrus HD-OCT Optical Coherence Tomographer, Model 4000 (K083291; K111157). The CIRRUS photo includes the fluorescein angiography (FA), and indocyanine green angiography (ICGA) functionalities of the Carl Zeiss Meditec FF450 plus Fundus Camera (K011877) and also contains filters for Fundus Autofluorescence. Filters for Fluorescein Angiography, ICG Angiography, and Fundus Autofluorescence are available in the Topcon TRC-NW8F (K100207). The Topcon 3D Optical Coherence Tomography 3D OCT-2000 (K092470), like the CIRRUS photo, incorporates a high resolution fundus camera with a Spectral Domain Optical Coherence Tomographer.

The CIRRUS photo is therefore substantially equivalent to the predicate devices, i.e., the Carl Zeiss Meditec VISUCAM PRO NM Digital Camera (K052268), the Carl Zeiss Meditec Cirrus HD-OCT, Model 4000 (K083291; K111157), the Carl Zeiss Meditec FF450 plus Fundus Camera (K011877), the Topcon TRC-NW8F (K100207), and the Topcon 3D OCT-2000 (K092470).

BRIEF SUMMARY OF NONCLINICAL AND CLINICAL TESTS AND RESULTS

The CIRRUS photo has been designed and tested to the applicable standards for electrical and optical safety and verified to established specifications. In addition, the following clinical testing, which includes repeatability and reproducibility, was performed.

CLINICAL TESTING

Two prospective studies were conducted to determine comparability, repeatability and reproducibility of the measurement data between the CIRRUS photo and Cirrus HD-OCT Model 4000 instruments.

NORMAL EYES STUDY

Sixty-three normal subjects were enrolled in a study to evaluate the equivalence of the means of 31 measurement parameters: retinal nerve fiber layer (RNFL) thickness (17 parameters), optic nerve head (ONH) (5 parameters), and macular thickness (9 parameters) between the CIRRUS photo and Cirrus HD-OCT Model 4000. The study was divided into two phases. Thirty subjects were enrolled in Phase 1 that evaluated inter-operator variability. Three Optic Disc Cube 200x200 scans were taken on one eye and three Macular Cube 512x128 scans were taken on the fellow eye by each of the four operators using one Cirrus HD-OCT Model 4000 and one CIRRUS photo instrument. Thirty-three subjects were enrolled in Phase 2 that evaluated inter-device variability. Three Optic Disc Cube 200x200 scans were taken on one eye and three

Macular Cube 512x128 scans were taken on the fellow eye from each of the four Cirrus HD-OCT Model 4000 instruments and each of the four CIRRUS photo instruments by one operator. Subjects could not participate in both phases.

DISEASED EYES STUDY

Seventy-three subjects with either macular disease or glaucoma were enrolled in a study to evaluate the equivalence of the means of 31 measurement parameters: retinal nerve fiber layer (RNFL) thickness (17 parameters), optic nerve head (ONH) (5 parameters), and macular thickness (9 parameters) between the CIRRUS photo and Cirrus HD-OCT Model 4000. The study was divided into two study arms; study arm 1 enrolled subjects with retina disease and study arm 2 enrolled subjects with glaucoma. Each study arm had two phases; phase 1evaluated inter-device variability and phase 2 evaluated inter-operator variability. Subjects could not participate in both phases of the study.

Nineteen subjects with retinal disease were enrolled in the inter-device phase of the study. Three Macular Cube 512x128 scans were taken by one operator using four Cirrus HD-OCT Model 4000 and four CIRRUS photo instruments. Nineteen different subjects with retinal disease were enrolled in the inter-operator phase of the study. Three Macular Cube 512x128 scans were taken by four operators using one Cirrus HD-OCT Model 4000 and one CIRRUS photo instrument.

Seventeen subjects with glaucoma were enrolled in the inter-device phase of the study. Three Optic Disc Cube 200x200 scans were taken by one operator using four Cirrus HD-OCT Model 4000 and four CIRRUS photo instruments. Eighteen subjects with glaucoma were enrolled in the inter-operator phase of the study. Three Optic Disc Cube 200x200 scans were taken by four operators using one Cirrus HD-OCT Model 4000 and one CIRRUS photo instrument.

DATA ANALYSIS

For each of the two study devices and each measurement parameter, the mean of the available measurements was calculated for each study eye. The difference in each of the 31 measurement parameters between the CIRRUS photo and Cirrus HD-OCT Model 4000 were calculated for each study eye. The mean difference, the corresponding 95% confidence intervals, and 95% limits of agreement were calculated for each measurement parameter. As the inter-operator phase utilized only one device, only the results for the inter-device phase are presented in Tables 1 and 2 for the normal and diseased eye studies, respectively.

The mean values of the 31 thickness parameters were very similar for the two devices. The results of these two studies support the incorporation of the normative databases established with the Cirrus HD-OCT Model 4000 instrument into the CIRRUS photo instrument with an adjustment based on regression analysis.

Additionally, analysis of variance (ANOVA) with random effect models was used to evaluate the repeatability, inter-device variability and inter-operator variability of each measurement parameter for the CIRRUS photo. The repeatability and reproducibility standard deviation (SD) and limits for the CIRRUS photo are shown in Tables 3 and 4 for the normal and diseased eyes studies, respectively. Cirrus photo showed good repeatability and reproducibility for both normal and diseased eyes.

TABLE 1

MEAN DIFFERENCE IN RNFL, ONH AND MACULAR THICKNESS MEASUREMENTS BETWEEN CIRRUS PHOTO AND CIRRUS HD-OCT OPTICAL COHERENCE TOMOGRAPHER, MODEL 4000 (NORMAL EYES)

	Cirrus 4000 Mean (SD)	Cirrus photo Mean (SD)	Difference Mean (SD)	95% Confidence Interval of Mean Difference	95% Limits of Agreement
RNFL Parameter	N = 33	N = 33	N = 33		
Average RNFL Thickness (μm)	94.3 (9.7)	93.7 (9.8)	0.6 (1.2)	(0.2, 1.0)	(-1.7, 2.9)
Temporal (μm)	68.8 (13.1)	68.4 (12.3)	0.4 (1.9)	(-0.3, 1.0)	(-3.3, 4.1)
Superior (μm)	119.3 (12.2)	121.0 (12.7)	-1.7 (2.4)	(-2.5, -0.8)	(-6.3, 2.9)
Nasal (μm)	69.8 (15.9)	68.2 (16.8)	1.6 (3.0)	(0.6, 2.7)	(-4.3, 7.6)
Inferior (μm)	119.4 (17.4)	117.5 (16.8)	1.9 (2.9)	(0.9, 2.9)	(-3.7, 7.5)
Clock hour 9 (μm)	53.3 (9.8)	53.8 (8.9)	-0.5 (2.1)	(-1.2, 0.3)	(-4.6, 3.6)
Clock hour 10 (μm)	82.0 (18.7)	83.8 (17.6)	-1.7 (3.1)	(-2.8, -0.6)	(-7.9, 4.4)
Clock hour 11 (μm)	134.8 (24.2)	137.4 (23.5)	-2.6 (4.1)	(-4.0, -1.2)	(-10.6, 5.4)
Clock hour 12 (μm)	116.5 (20.8)	117.1 (21.4)	-0.6 (4.5)	(-2.2, 1.0)	(-9.3, 8.2)
Clock hour 1 (μm)	106.5 (15.0)	108.3 (15.8)	-1.8 (4.7)	(-3.5, -0.1)	(-11.1, 7.5)
Clock hour 2 (μm)	86.9 (21.3)	83.5 (21.7)	3.4 (3.9)	(2.0, 4.8)	(-4.2, 10.9)
Clock hour 3 (μm)	58.2 (12.3)	56.1 (13.0)	2.1 (3.5)	(0.9, 3.4)	(-4.8, 9.0)
Clock hour 4 (μm)	64.3 (18.1)	64.8 (19.2)	-0.5 (3.8)	(-1.8, 0.9)	(-8.0, 7.0)
Clock hour 5 (μm)	93.0 (18.8)	93.1 (18.9)	-0.2 (4.3)	(-1.7, 1.4)	(-8.6, 8.2)
Clock hour 6 (μm)	130.5 (31.2)	130.3 (29.2)	0.2 (5.6)	(-1.7, 2.2)	(-10.7, 11.1)
Clock hour 7 (μm)	134.8 (18.5)	129.1 (17.7)	5.7 (4.3)	(4.2, 7.2)	(-2.7, 14.1)
Clock hour 8 (μm)	71.0 (14.5)	67.6 (14.1)	3.4 (3.5)	(2.2, 4.7)	(-3.4, 10.2)
ONH Parameters	N = 33	N = 33	N = 33		
Average Cup-to-Disc Ratio	0.455 (0.158)	0.466 (0.154)	-.012 (0.012)	(-.016, -.007)	(-.035, 0.011)
Vertical Cup-to-Disc Ratio	0.430 (0.153)	0.440 (0.152)	-.010 (0.013)	(-.015, -.005)	(-.036, 0.016)
Disc Area (mm^2)	1.753 (0.294)	1.822 (0.310)	-.068 (0.034)	(-.081, -.056)	(-.135, -.001)
Rim Area (mm^2)	1.317 (0.177)	1.352 (0.186)	-.034 (0.027)	(-.044, -.025)	(-.088, 0.019)
Cup Volume (mm^3)	0.1293 (0.1246)	0.1382 (0.1309)	-.0089 (0.0104)	(-.0126, -.0052)	(-.0292, 0.0114)
Macular Thickness Parameters	N = 33	N = 33	N = 33		
Central Subfield (μm)	265.0 (23.7)	262.8 (23.4)	2.2 (2.1)	(1.5, 3.0)	(-1.8, 6.3)
Inner Temporal (μm)	310.2 (13.7)	308.6 (13.2)	1.6 (2.5)	(0.7, 2.5)	(-3.3, 6.6)
Inner Superior (μm)	324.6 (14.8)	323.6 (14.1)	1.1 (3.1)	(-0.0, 2.2)	(-5.1, 7.2)
Inner Nasal (μm)	328.8 (15.4)	326.6 (14.6)	2.2 (3.0)	(1.2, 3.3)	(-3.6, 8.1)
Inner Inferior (μm)	320.7 (15.7)	319.1 (14.9)	1.6 (2.8)	(0.6, 2.5)	(-3.9, 7.0)
Outer Temporal (μm)	260.5 (13.6)	261.0 (13.3)	-0.6 (1.9)	(-1.2, 0.1)	(-4.3, 3.2)
Outer Superior (μm)	279.7 (13.1)	279.7 (12.7)	-0.0 (2.1)	(-0.8, 0.7)	(-4.1, 4.0)
Outer Nasal (μm)	299.4 (16.1)	298.9 (15.2)	0.5 (2.2)	(-0.3, 1.3)	(-3.7, 4.7)
Outer Inferior (μm)	266.2 (14.0)	266.1 (13.4)	0.2 (2.2)	(-0.6, 0.9)	(-4.1, 4.4)

For the inter-device phase of the study, 33 subjects were enrolled.

For each of the two study devices, the average of measurements from different units were calculated for each eye and this average was treated as the measurement for the corresponding eye.

Difference = Cirrus-4000 - Cirrus-photo.

95% Confidence Interval of Mean Difference = mean ± 1.96 ×SE. 95% Limits of Agreement = mean ± 1.96 ×SD.

TABLE 2
MEAN DIFFERENCE IN RNFL, ONH AND MACULAR THICKNESS MEASUREMENTS BETWEEN CIRRUS PHOTO AND CIRRUS HD-OCT OPTICAL COHERENCE TOMOGRAPHER, MODEL 4000 (DISEASED EYES)

	Cirrus 4000 Mean (SD)	Cirrus photo Mean (SD)	Difference Mean (SD)	95% Confidence Interval of Mean Difference	95% Limits of Agreement
RNFL Parameter	**N = 17**	**N = 17**	**N = 17**		
Average RNFL Thickness (μm)	63.8 (10.0)	63.1 (9.6)	0.8 (1.3)	(0.1, 1.4)	(-1.7, 3.2)
Temporal (μm)	47.1 (8.3)	48.1 (8.0)	-0.9 (1.7)	(-1.8, -0.1)	(-4.2, 2.4)
Superior (μm)	78.5 (16.7)	78.9 (17.7)	-0.3 (1.8)	(-1.3, 0.6)	(-3.9, 3.3)
Nasal (μm)	58.7 (7.3)	55.8 (5.8)	2.9 (2.9)	(1.3, 4.4)	(-2.9, 8.6)
Inferior (μm)	70.8 (18.1)	69.4 (16.9)	1.4 (2.3)	(0.2, 2.6)	(-3.1, 5.9)
Clock hour 9 (μm)	41.6 (8.7)	43.2 (8.8)	-1.6 (2.0)	(-2.6, -0.5)	(-5.6, 2.4)
Clock hour 10 (μm)	52.4 (12.8)	53.8 (14.2)	-1.3 (2.5)	(-2.6, -0.0)	(-6.3, 3.6)
Clock hour 11 (μm)	78.9 (20.9)	80.3 (21.5)	-1.4 (2.8)	(-2.9, 0.0)	(-7.0, 4.1)
Clock hour 12 (μm)	81.4 (23.1)	81.0 (24.6)	0.4 (4.0)	(-1.7, 2.5)	(-7.5, 8.3)
Clock hour 1 (μm)	75.3 (17.5)	75.4 (17.8)	-0.1 (1.9)	(-1.1, 0.8)	(-3.8, 3.6)
Clock hour 2 (μm)	66.5 (9.2)	63.8 (9.3)	2.7 (3.0)	(1.2, 4.2)	(-3.1, 8.5)
Clock hour 3 (μm)	55.2 (10.0)	51.1 (7.7)	4.1 (3.9)	(2.1, 6.1)	(-3.5, 11.7)
Clock hour 4 (μm)	54.4 (7.8)	52.8 (6.7)	1.6 (4.3)	(-0.5, 3.8)	(-6.7, 10.0)
Clock hour 5 (μm)	64.7 (16.7)	64.7 (17.4)	-0.1 (3.9)	(-2.0, 1.9)	(-7.6, 7.5)
Clock hour 6 (μm)	75.3 (20.5)	74.5 (18.6)	0.8 (5.5)	(-2.0, 3.6)	(-9.9, 11.5)
Clock hour 7 (μm)	72.6 (21.3)	69.0 (18.8)	3.5 (4.3)	(1.3, 5.8)	(-4.9, 12.0)
Clock hour 8 (μm)	47.5 (10.2)	47.4 (8.8)	0.1 (2.8)	(-1.3, 1.6)	(-5.4, 5.7)
ONH Parameters	**N = 17**	**N = 17**	**N = 17**		
Average Cup-to-Disc Ratio	0.732 (0.097)	0.738 (0.093)	-.006 (0.007)	(-.010, -.002)	(-.021, 0.008)
Vertical Cup-to-Disc Ratio	0.736 (0.094)	0.742 (0.088)	-.006 (0.012)	(-.013, -.000)	(-.031, 0.018)
Disc Area (mm^2)	1.758 (0.489)	1.853 (0.523)	-.095 (0.045)	(-.118, -.072)	(-.184, -.006)
Rim Area (mm^2)	0.770 (0.216)	0.795 (0.222)	-.024 (0.016)	(-.032, -.016)	(-.055, 0.006)
Cup Volume (mm^3)	0.4105 (0.2230)	0.4419 (0.2376)	-.0315 (0.0181)	(-.0408, -.0222)	(-.0669, 0.0039)
Macular Thickness Parameters	**N = 19**	**N = 19**	**N = 19**		
Central Subfield (μm)	343.8 (107.9)	341.4 (108.8)	2.4 (5.2)	(-0.1, 4.9)	(-7.9, 12.6)
Inner Temporal (μm)	366.4 (92.7)	365.0 (94.4)	1.4 (9.3)	(-3.1, 5.9)	(-16.8, 19.6)
Inner Superior (μm)	364.6 (86.3)	364.7 (87.9)	-0.1 (5.4)	(-2.7, 2.5)	(-10.7, 10.5)
Inner Nasal (μm)	366.1 (83.7)	366.5 (85.3)	-0.4 (6.8)	(-3.6, 2.9)	(-13.6, 12.9)
Inner Inferior (μm)	365.1 (85.7)	365.1 (86.5)	-0.0 (5.1)	(-2.5, 2.4)	(-10.0, 10.0)
Outer Temporal (μm)	283.7 (44.7)	285.3 (45.6)	-1.6 (2.3)	(-2.7, -0.5)	(-6.0, 2.8)
Outer Superior (μm)	299.6 (49.5)	301.7 (50.0)	-2.1 (2.8)	(-3.5, -0.7)	(-7.7, 3.5)
Outer Nasal (μm)	308.2 (45.7)	310.0 (46.6)	-1.8 (2.6)	(-3.0, -0.5)	(-6.8, 3.3)
Outer Inferior (μm)	285.7 (46.6)	288.1 (48.5)	-2.4 (3.8)	(-4.2, -0.5)	(-9.9, 5.1)

For the inter-device phase of the study, 17 glaucomatous eyes and 19 eyes with retinal disease were enrolled.
For each of the two study devices, the average of measurements from different units were calculated for each eye and this average was treated as the measurement for the corresponding eye.
Difference = Cirrus-4000 - Cirrus-photo.
95% Confidence Interval of Mean Difference = mean ± 1.96 ×SE. 95% Limits of Agreement = mean ± 1.96 ×SD.

TABLE 3.
CIRRUS PHOTO REPEATABILITY AND REPRODUCIBILITY IN MEASURING RNFL, ONH AND MACULAR THICKNESS (NORMAL EYES)

	Repeatability		Reproducibility		COV %	
	SD	Limit	SD	Limit	Based on Repeatability	Based on Reproducibility
RNFL Parameter						
Average RNFL Thickness (μm)	1.4634	4.0974	2.1899	6.1319	1.5660	2.3436
Temporal (μm)	3.1109	8.7106	3.4480	9.6544	4.6498	5.1536
Superior (μm)	4.0906	11.4538	5.2156	14.6038	3.4418	4.3884
Nasal (μm)	2.9302	8.2045	3.7041	10.3714	4.2513	5.3742
Inferior (μm)	3.4906	9.7737	4.8547	13.5930	2.9296	4.0744
Clock hour 9 (μm)	2.9861	8.3610	3.5083	9.8232	5.5946	6.5730
Clock hour 10 (μm)	4.2639	11.9388	4.6703	13.0768	5.2313	5.7299
Clock hour 11 (μm)	4.6518	13.0249	6.5183	18.2512	3.5278	4.9434
Clock hour 12 (μm)	6.6529	18.6281	7.7500	21.7000	5.6827	6.6198
Clock hour 1 (μm)	5.9988	16.7968	7.5104	21.0291	5.5767	6.9818
Clock hour 2 (μm)	5.1422	14.3981	6.4081	17.9426	6.0570	7.5481
Clock hour 3 (μm)	2.8467	7.9707	3.6839	10.3149	5.0520	6.5378
Clock hour 4 (μm)	3.4901	9.7722	4.2787	11.9803	5.3322	6.5371
Clock hour 5 (μm)	5.3422	14.9581	7.2244	20.2284	5.5214	7.4668
Clock hour 6 (μm)	5.9229	16.5841	8.1056	22.6956	4.4538	6.0951
Clock hour 7 (μm)	5.4060	15.1368	7.5886	21.2480	4.2341	5.9435
Clock hour 8 (μm)	3.8676	10.8293	4.9749	13.9296	5.8758	7.5580
ONH Parameters						
Cup Disc Ratio	0.0236	0.0660	0.0245	0.0685	5.1582	5.3539
Vertical CD Ratio	0.0277	0.0774	0.0289	0.0809	6.3477	6.6278
Disc Area (mm^2)	0.0888	0.2486	0.1009	0.2825	4.8833	5.5498
Rim Area (mm^2)	0.0483	0.1352	0.0626	0.1752	3.5837	4.6455
Cup Volume (mm^3)	0.0105	0.0294	0.0124	0.0349	7.5869	9.0060
Macular Thickness Parameters						
Central Subfield (μm)	1.6398	4.5914	2.7756	7.7718	0.6308	1.0677
Inner Temporal (μm)	2.0716	5.8006	3.4834	9.7536	0.6683	1.1238
Inner Superior (μm)	2.1805	6.1054	3.4096	9.5470	0.6732	1.0527
Inner Nasal (μm)	2.1538	6.0307	3.1998	8.9594	0.6591	0.9792
Inner Inferior (μm)	2.0770	5.8156	3.2125	8.9951	0.6484	1.0029
Outer Temporal (μm)	1.7440	4.8833	2.8387	7.9483	0.6648	1.0820
Outer Superior (μm)	1.9601	5.4884	2.7409	7.6744	0.6997	0.9784
Outer Nasal (μm)	1.9932	5.5811	2.9532	8.2689	0.6662	0.9871
Outer Inferior (μm)	2.2541	6.3115	3.2616	9.1325	0.8427	1.2194

Repeatability SD is the standard deviation under repeatability conditions. Repeatability Limit is the upper 95 % limit for the difference between repeated results under repeatability conditions. Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 × Repeatability SD. Reproducibility SD is the standard deviation under reproducibility conditions. It was estimated by the square root of the sum of repeatability variance and the variance components of operator, operator*subjects, device and device*subjects. Reproducibility Limit is the upper 95 % limit for the difference between repeated results under reproducibility conditions. Reproducibility Limit = 2.8 × Reproducibility SD.

COV = Coefficient of variation = SD ÷Mean. ×100. SD is either Repeatability SD or Reproducibility SD.

TABLE 4
CIRRUS PHOTO REPEATABILITY AND REPRODUCIBILITY IN MEASURING RNFL, ONH AND MACULAR THICKNESS (DISEASED EYES)

	Repeatability		Reproducibility		COV %	
	SD	Limit	SD	Limit	Based on Repeatability	Based on Reproducibility
RNFL Parameter						
Average RNFL Thickness (μm)	1.4634	4.0976	1.8796	5.2629	2.2840	2.9336
Temporal (μm)	2.2956	6.4276	2.5546	7.1529	4.7043	5.2351
Superior (μm)	2.8264	7.9140	3.5281	9.8787	3.5930	4.4850
Nasal (μm)	2.8991	8.1176	3.9553	11.0748	4.9599	6.7668
Inferior (μm)	2.5395	7.1106	2.9880	8.3664	3.6115	4.2493
Clock hour 9 (μm)	2.4813	6.9476	2.8941	8.1034	5.5483	6.4713
Clock hour 10 (μm)	3.4895	9.7705	3.9555	11.0755	6.4194	7.2768
Clock hour 11 (μm)	3.8494	10.7784	4.0928	11.4599	4.9950	5.3108
Clock hour 12 (μm)	4.4919	12.5774	5.7878	16.2060	5.4955	7.0809
Clock hour 1 (μm)	3.9406	11.0336	4.6576	13.0414	5.1041	6.0328
Clock hour 2 (μm)	3.4231	9.5848	3.9783	11.1394	5.1747	6.0140
Clock hour 3 (μm)	3.4882	9.7670	5.0632	14.1771	6.5627	9.5259
Clock hour 4 (μm)	3.8452	10.7666	4.7855	13.3993	6.8533	8.5291
Clock hour 5 (μm)	3.8818	10.8691	4.5783	12.8192	5.6594	6.6747
Clock hour 6 (μm)	3.9587	11.0845	4.3994	12.3182	5.3266	5.9195
Clock hour 7 (μm)	3.6302	10.1644	4.6261	12.9530	5.3360	6.7998
Clock hour 8 (μm)	2.5716	7.2005	3.0180	8.4503	5.4299	6.3724
ONH Parameters						
Cup Disc Ratio	0.0276	0.0774	0.0278	0.0777	3.7279	3.7449
Vertical CD Ratio	0.0307	0.0860	0.0313	0.0877	4.0501	4.1308
Disc Area (mm^2)	0.0584	0.1635	0.0624	0.1746	3.0618	3.2703
Rim Area (mm^2)	0.0367	0.1027	0.0395	0.1106	4.5529	4.9033
Cup Volume (mm^3)	0.0220	0.0615	0.0247	0.0692	4.8135	5.4138
Macular Thickness Parameters						
Central Subfield (μm)	5.6224	15.7427	7.6068	21.2992	1.5989	2.1632
Inner Temporal (μm)	4.3574	12.2007	5.1083	14.3032	1.1857	1.3900
Inner Superior (μm)	4.5687	12.7923	5.3448	14.9653	1.2562	1.4696
Inner Nasal (μm)	4.1606	11.6498	6.3917	17.8968	1.1298	1.7356
Inner Inferior (μm)	5.4349	15.2178	5.7159	16.0046	1.5167	1.5951
Outer Temporal (μm)	2.9954	8.3870	3.3484	9.3755	1.0367	1.1588
Outer Superior (μm)	2.8585	8.0038	3.3155	9.2835	0.9475	1.0989
Outer Nasal (μm)	2.7562	7.7173	3.4669	9.7073	0.8862	1.1147
Outer Inferior (μm)	4.2730	11.9645	4.6956	13:1476	1.5132	1.6628

Repeatability SD is the standard deviation under repeatability conditions. Repeatability Limit is the upper 95 % limit for the difference between repeated results under repeatability conditions. Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 × Repeatability SD. Reproducibility SD is the standard deviation under reproducibility conditions. It was estimated by the square root of the sum of repeatability variance and the variance components of operator, operator*subjects, device and device*subjects. Reproducibility Limit is the upper 95 % limit for the difference between repeated results under reproducibility conditions. Reproducibility Limit = 2.8 × Reproducibility SD.

COV = Coefficient of variation = SD ÷Mean. ×100. SD is either Repeatability SD or Reproducibility SD.

SUMMARY

As described in this 510(k) Summary, all testing deemed necessary was conducted on the CIRRUS photo 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

JUN 18 2012

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

Re: K112184
Trade/Device Name: Cirrus photo; Model 600 and 800
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO, HKI
Dated: June 14, 2012
Received: June 15, 2012

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,

Kesia 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

510(k) Number (if known): K112184

Device Name(s): CIRRUS photo

Indications for Use:

The CIRRUS photo (Models 600 and 800) is a non-contact, high resolution tomographic and biomicroscopic imaging device that incorporates a digital camera which is suitable for photographing, displaying and storing the data of the retina and surrounding parts of the eye to be examined under mydriatic and non-mydriatic conditions.

These photographs support the diagnosis and subsequent observation of eye diseases which can be visually monitored and photographically documented. The CIRRUS photo is indicated for *in vivo* viewing, axial cross sectional, and three-dimensional imaging and measurement of posterior ocular structures, including retina, retinal nerve fiber layer, macula, and optic disc as well as imaging of anterior ocular structures, including the cornea.

It also includes a Retinal Nerve Fiber Layer (RNFL), Optic Nerve Head (ONH), and Macular Normative Database which is a quantitative tool for the comparison of retinal nerve fiber layer, optic nerve head, and the macula in the human retina to a database of known normal subjects. It 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__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __1__ of __1__

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

510(k) Number K112184