DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

July 10, 2015

Carl Zeiss Meditec, Inc.
Ms. Christine Dunbar
Ophthalmic Systems
Manager, Regulatory Submissions
5160 Hacienda Drive
Dublin, California 94568

Re: K143275
Trade/Device Name: IOLMaster 700
Regulation Number: 21 CFR 886.1850
Regulation Name: Ac-Powered Slitlamp Biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: June 4, 2015
Received: June 5, 2015

Dear Ms. Dunbar:

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 contact the Division of Industry and Consumer Education 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. 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 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 Industry and Consumer Education 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 Y. Alexander -A

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

Enclosure

Section 1: Indications for Use – IOLMaster 700

510(k) Number (if known):_____

Device Name(s): IOLMaster 700

Indications for Use:

The IOLMaster 700 is intended for biometric measurements and visualization of ocular structures. The measurements and visualization assist in the determination of the appropriate power and type of intraocular lens. The IOLMaster 700 measures:

- Lens thickness
- Corneal curvature and thickness
- Axial length
- Anterior chamber depth
- Pupil diameter
- White-to-white distance (WTW)

For visualization, the IOLMaster 700 employs optical coherence tomography (OCT) to obtain two-dimensional images of ocular structures of the anterior and posterior segments of the eye.

The Reference Image functionality is intended for use as a preoperative and postoperative image capture tool.

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)

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Section 2: 510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter's name, address, telephone number, contact person, and date summary prepared:

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Date Prepared: June 29, 2015

Name of device, including trade name and classification name

1.	Trade/Proprietary Name:	a. IOLMaster 700
2.	Common/Usual Name:	a. Biometer
3.	Classification Name:	a. AC-powered, biomicroscope
4.	Product Code and Class:	a. HJO – Class II
5.	Classification Number:	a. 21 CFR 886.1850

Predicate Devices

The IOLMaster 700 is similar in function and application and is used in the preparation phase of cataract surgery as the following predicate devices:

- the IOLMaster 500 (K122418) - the primary predicate as it has the most similar intended use and characteristics,
- the Lenstar LS 900 (K082891) is an additional (secondary) predicate to support the two new measurements featured on the IOLMaster 700,
- additionally, the IOLMaster 500 as part of the ZEISS Cataract Suite markerless (K141068) for the Reference Imaging feature.

- The Visante OCT (K051789) is provided as a reference device to support the OCT function of the IOLMaster 700.

The IOLMaster 700 provides similar basic measurement features as the primary predicate, IOLMaster 500 (K122418). Additionally, the IOLMaster 700 measures the corneal thickness and lens thickness which is similar to the Lenstar LS 900 (K082891) manufactured by Haag- Streit. All three devices are intended to provide measurements of the human eye and provide IOL power calculations to aid the physician prior to cataract surgery.

A comparison of the features, indications for use, and technological characteristics of the IOLMaster 700 is intended to establish substantial equivalence to the previously cleared predicate devices, the IOLMaster 500 and the Lenstar LS 900.

Device Description

The IOLMaster 700 device is a computerized biometry device consisting of an OCT system, a Keratometer system, and a camera for the purposes of:

- measuring distances within the human eye along the visual axis (e.g. axial length, lens thickness, anterior chamber depth),
- measuring the corneal surface with a keratometer,
- measuring distances at the front of the eye with a camera (e.g. white-to-white distance).

The IOLMaster 700 is used for visualization and measurement of ocular structures mainly required for the preparation of cataract surgeries to calculate the refractive power of the intraocular lens (IOL) to be implanted. The IOLMaster 700 device includes a swept source frequency domain optical coherence tomography (OCT) module capable of acquiring tomograms of the eye. The axial measurements are based on those tomograms.

The IOLMaster 700 device is operated via multi touch monitor and alternatively with computer mouse and keyboard. A joystick on the measuring head is used for manual alignment of the device to the patient's eye.

Indications for Use

The IOLMaster 700 is intended for biometric measurements and visualization of ocular structures. The measurements and visualization assist in the determination in the appropriate power and type of intraocular lens.
The IOLMaster 700 measures:

- Lens thickness
- Corneal curvature and thickness
- Axial length
- Anterior chamber depth

- Pupil diameter
- White-to-white distance (WTW)

For visualization, the IOLMaster 700 employs optical coherence tomography (OCT) to obtain two-dimensional images of ocular structures of the anterior and posterior segments of the eye.

The Reference Image functionality is intended for use as a preoperative and postoperative image capture tool.

Comparison of Technological Characteristics

The comparison of the technological characteristics to the predicates is as follows:

IOLMaster 700:

The IOLMaster 700 is a new biometry device providing the same basic measuring features as the IOLMaster 500 and in addition, measures central corneal thickness and lens thickness. It also includes the Reference Image functionality for use in the ZEISS Cataract Suite markerless workflow.

The IOLMaster 700 contains a swept source frequency domain optical coherence tomography (OCT) module that uses a tunable laser [1055 nm]. It is based on an interference optical method known as partial coherence interferometry (PCI). Multiple A-scans provide B-scans that are displayed as cross-sectional images of the human eye and are used to obtain axial measurements: corneal thickness, anterior chamber depth, lens thickness, and axial length. Corneal curvature and white-to-white measurements use the same technology as the IOLMaster 500.

IOLMaster 500 (K122418):

The IOLMaster 700 provides similar basic measurement features as the primary predicate, IOLMaster 500 (K122418). Both devices are combined biometry instruments used to take measurements of the human eye. It provides measurements of the following eye parameters: axial length, corneal curvature, anterior chamber depth, and white-to-white distance is similar to the measurements from the IOLMaster 700. The axial length measurement is based on partial coherence interferometry (PCI) A-scans as it is in the IOLMaster 700. The IOLMaster 500 uses a multimode laser diode [780 nm] to realize time domain interferometry (dual beam principle).

Anterior chamber depth measurements are based on a slit lamp module, whereas the IOLMaster 700 extracts anterior chamber depth from OCT scans similar to the Lenstar LS 900 (K082891) system. Corneal curvature is measured by a telecentric keratometry. White-to-white is obtained using a camera.

Lenstar LS 900 (K082891):

The IOLMaster 700 measures the corneal thickness and lens thickness which is similar to the Lenstar LS 900 (K082891) manufactured by Haag-Streit. Both devices generate A-scans. The technology used by the Lenstar LS 900 includes super luminescence diode [820 nm] as the laser source, A-scans based on Optical Low-Coherence Reflectometry (OLCR, principle of OCT) and a distance dependent

keratometer.

Like the IOLMaster 700, the Lenstar LS 900 is used for obtaining ocular measurements and performing calculations to assist in the determination of the appropriate power and type of IOL for implantation after cataract removal.

Visante OCT (K051789):

The reference device, Visante OCT and the IOLMaster 700 OCT both acquire and visualize cross-sectional tomograms of the anterior eye segment using optical coherence tomography (OCT).

Table 1 Summary of Comparison between IOLMaster 700 and IOLMaster 500

Feature or Function	IOLMASTER 700 *SUBJECT DEVICE*	IOLMASTER 500 *PRIMARY PREDICATE - K122418*
Indications for Use	The IOLMaster 700 is intended for biometric measurements and visualization of ocular structures. The measurements and visualization assist in the determination of the appropriate power and type of intraocular lens. The IOLMaster 700 measures: • Lens thickness • Corneal curvature and thickness • Axial length • Anterior chamber depth • Pupil diameter • White-to-white distance (WTW) For visualization, the IOLMaster 700 employs optical coherence tomography (OCT) to obtain two-dimensional images of ocular structures of the anterior and posterior segments of the eye. The Reference Image functionality is intended for use as a preoperative and postoperative image capture tool.	The IOLMaster is intended for the biometric determination of ocular measurements of axial length, anterior chamber depth, corneal radius, white-to-white (WTW), and for the measurement of pupil size and deviation of the visual axis from the center of the pupil. For patients who are candidates for intraocular lens (IOL) implantation, the device also performs calculations to assist physicians in determining the appropriate IOL power and type for implantation. This device is intended for use by physicians and eye-care professionals and may only be used under the supervision of a physician ***Additional IOLMaster 500 Predicate - K141068*** IOLMaster 500 Indications for Use remains unchanged from K122418.
Reference Image	Included feature (software license) Green LEDs for green light illumination for image capturing of scleral vessels with internal camera.	Option Reference Image Feature cleared under K141068. Green LEDs for green light illumination for image capturing of scleral vessels with internal camera.
Principles of Operation	Optical coherence tomography (OCT) - Generation of B-Scans LED spot projection Image capture Image processing	Partial coherence interferometry (PCI) – Generation of A-Scans. LED spot projection Slit Lamp Illumination Image capture Image processing Import of ultrasound measurements.

Feature or Function	IOLMASTER 700 *SUBJECT DEVICE*	IOLMASTER 500 *PRIMARY PREDICATE - K122418*
Cross-sectional Imaging Technology	Swept source laser [1055 nm], frequency domain optical coherence interferometry (OCT principle), acquires 2000 A-scans /second, Two orthogonal scan units. Multiple A-scans provide a B-scan (2D Imaging).	Multimode laser diode [780 nm], Time domain interferometry (dual beam principle),
Fixation Light	LED [660 nm]	LED [590 nm]
Keratometry	Telecentric keratometry = distance independent Light spot projection (infrared LEDs)	Telecentric keratometry = distance independent Light spot projection (infrared LEDs)
AL (mm):	Swept source laser [1055 nm], Spectral domain interferometry (OCT principle), Multiple A-scans provide a B-scan (2D image).	Multimode laser diode [780 nm], Time domain interferometry (dual beam principle), Measurement can be imported from ultrasound system.
ACD (mm):	Swept source laser [1055 nm], Spectral domain interferometry (OCT principle), Multiple A-scans provide a B-scan (2D image).	Slit lamp principle
CCT, LT (mm):	Swept source laser [1055 nm], Spectral domain interferometry (OCT principle). Multiple A-scans provide a B-scan (2D image).	Not available.
WTW, Pupil diameter (mm):	Infrared LEDs illumination and image capturing of the eye with internal camera.	Infrared LEDs illumination and image capturing of the eye with internal camera.
Computational formulas	Haigis Suite* (*includes Haigis, Haigis-L and Haigis-T) Hoffer Q Holladay 2 SRK®/T	Haigis, Haigis-L HofferQ Holladay 1 Holladay 2 SRK®/T

Feature or Function	IOLMASTER 700 *SUBJECT DEVICE*	IOLMASTER 500 *PRIMARY PREDICATE - K122418*
		SRK® II Phakic implants Corneal K's correction (for eyes after refractive surgery)
Ultrasound link Option "Sonolink"	Not available	Available

Performance Data

Biocompatibility:

The IOLMaster 700 has two patient-contact components; the patient chin rest and the forehead rest. Biocompatibility testing was conducted according to ISO 10993-1:2009 Biological evaluation of medical devices. The material tested was compliant with the requirements in ISO10993-1:2009.

Electrical Safety and EMC:

Electrical safety and electromagnetic compatibility (EMC) for the IOLMaster 700 was evaluated. Conformance to standards for electrical safety (IEC 60601-1:2007), electromagnetic compatibility (IEC 60601-1-2:2007) and other recognized standards was demonstrated.

Optical radiation safety:

Optical radiation safety of the IOLMaster 700 was evaluated. Conformance to light hazard protection for ophthalmic instruments (ISO 15004-2:2007) and safety of laser products (IEC 60825-1:2007) was demonstrated.

Software Verification and Validation Testing:

The IOLMaster 700 was tested according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005.

Clinical Studies:

Description of Study:

A non-significant risk clinical study was conducted at three sites to determine comparability of the measurements obtained from the IOLMaster 700 and the IOLMaster 500 and Lenstar LS 900, and to

determine the repeatability and reproducibility of the measurements of the IOLMaster 700.

A total of 120 eyes were enrolled to determine the comparability of the following parameters: axial length (AL), anterior chamber depth (ACD), central corneal thickness (CCT), lens thickness (LT), white-to-white (WTW) and keratometry [Radii R1 and R2, Cylinder (Cyl), Spherical Equivalent (SE), Axis (A)]. Only one eye of each subject was designed as the study eye.

The subjects with cataracts enrolled in the study ranged in age from 37 to 89 years; the mean was 68 years. The severity of the cataract density was determined by the clinical investigator and included mild (Grade 1, 83%), moderate (Grade 2, 15%) and severe (Grade 3, 2%). The study population included 54 males and 66 females (45%, 55%, respectively).

The study inclusion criteria required adult males or females who had been diagnosed with a cataract graded to be at least grade 1 and who were willing to participate in the study examination and measurements and give consent.

The study exclusion criteria included:

- Patients who were not capable of understanding the instructions of the investigator or to give their consent or who were unable to sit upright in front of the devices, with injuries to the forehead or chin;
- Patients with an inability to keep fixation as well as those who had eccentric fixation, nervous disposition, poor patient cooperation or those with tremor, nystagmus, or shortage of breath;
- Patients with insufficient corneal reflection for a keratometry or ACD measurement, i.e. due to serious tear film problems on the study eye or who had existing corneal abnormalities, e.g. corneal scars, keratoconus, degenerative diseases, active infection or inflammation in the study eye;
- Patients who did not remove their hard or soft contact lens within the required time period prior to undergoing study measurements or who had partial or complete covering of the cornea by eyelid or eyelid closure;
- Patients with previous refractive or other corneal surgery on the study eyes or implantation of a phakic intraocular lens in the study eye;
- Patients with morphological changes in the retinal anatomy in fovea region, e.g. vitreous hemorrhage, acute retinal detachment in the study eye.

Data Collection

The study employed three IOLMaster 700 devices, three IOLMaster 500 devices, and three Lenstar LS 900 devices; each of the three sites possessed one IOLMaster 700, one IOLMaster 500 and one Lenstar LS 900 for the duration of the study.

Subjects were examined with the three study devices in one session wherein the operators attempted to take five measurements with the IOLMaster 700 and one measurement with the IOLMaster 500 as well as the Lenstar LS 900 on each study eye.

Data Analysis

Prior to data analysis, scans were reviewed using the same quality criteria as described in the User Manual, Software Description. Specifically, the reviewers used the following criteria:

- Incorrect caliper placement by artifacts in B-scans (interfaces not detected correctly by the algorithm due to poor segmentation or floaters or other artifacts in the vitreous / anterior chamber)
- Blurred WTW image (scleral image not visible)
- Closed eyelid in any image
- Distorted or missing reflections in keratometry image (incomplete number of spots reflected from cornea or blurred reflections due to shading caused by eye lashes, eye lid or poor tear film)

For the agreement comparison, only the first acceptable IOLMaster 700 measurement out of five was used to analyze the difference between the IOLMaster 700 and the comparison device.

For analyzing keratometry, the resulting parameters spherical equivalent (SE) and cylinder (CYL) were calculated based on the existing values R1 [mm] and R2 [mm].

For each of the parameters AL, ACD, R1, R2, A, SE and CYL, the difference in measurement between IOLMaster 700 and IOLMaster 500 was calculated for each eye by subtracting the value of IOLMaster 500 from the value of IOLMaster 700.

Repeatability standard deviation (SD) was estimated by the square-root of the estimated variance due to measurement error based on the random effect ANOVA model. The repeatability limit (or repeatability) was estimated by the 95% confidence limit of the difference between two repeated measurements (Formula 1).The reproducibility SD was estimated by the square-root of sum of variance due to measurement error and variance due to study site.

The reproducibility limit (or reproducibility) was estimated by Formula 2:

1) Repeatability SD is the standard deviation under repeatability conditions.
   Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 × Repeatability SD.
   Repeated COV [%] = Coefficient of Variation = Repeatability SD ÷ Mean. (× 100). The mean was the estimated general mean in the random ANOVA model for the R&R calculation.
2) Reproducibility SD is the standard deviation calculated for the difference between individual measurement using different operators and instruments.
   Per ISO 5725-1 and ISO 5725-6, Reproducibility Limit = 2.8 × Reproducibility SD.

The Coefficient of Variability (COV) was calculated by the quotient of the standard deviation from repeatability and reproducibility and the mean of all used measurements.

As the Axis measurement in IOLMaster 700 serves only for the alignment of toric IOLs, only eyes with corneal astigmatism of 0.75 D and higher were analyzed.

Table 1 summarizes the descriptive statistics for differences between the IOLMaster 700 and the comparison devices (IOLMaster 500 and Lenstar LS 900).

The values from each instrument used in the calculation of those differences are shown in Table 2

(Descriptive Statistics Summary for Difference), and Table 3 (Mean Difference Between Devices with Limits of Agreement).

In Tables 1-3, the first acceptable measurement for each subject was considered for comparison of the IOLMaster 700 and comparison devices (IOLMaster 500 and Lenstar LS 900).

Table 1: Descriptive Statistics Summary - IOLMaster 700 and Comparison Devices

	IOLMaster 700				**IOLMaster 500**			
	n	Mean (SD)	Median	Min, Max	n	Mean (SD)	Median	Min, Max
Biometry mode								
AL [mm]	113	23.636 (1.820)	23.260	20.49, 34.56	113	23.632 (1.811)	23.250	20.53, 34.54
ACD [mm]	113	3.061 (0.415)	3.080	2.03, 4.12	113	3.044 (0.402)	3.020	2.09, 4.08
Keratometry mode								
R1, Radius in Flat Meridian [mm]	113	7.784 (0.250)	7.780	7.10, 8.80	113	7.783 (0.252)	7.780	7.12, 8.78
R2, Radius in Steep Meridian [mm]	113	7.610 (0.238)	7.610	6.99, 8.18	113	7.613 (0.238)	7.610	6.99, 8.15
SE [D]	113	43.175 (1.326)	43.170	39.36, 47.13	113	43.176 (1.329)	43.122	39.32, 47.06
Cyl [D]	113	0.969 (0.627)	0.870	0.00, 3.39	113	0.956 (0.663)	0.856	0.00, 3.24
A [°]	59	90.63 (68.224)	96	0, 187	59	89.22 (67.078)	89	-2, 188
WTW mode								
WTW [mm]	97	11.889 (0.407)	12.00	10.9, 12.9	97	12.024 (0.429)	12.00	11.0, 13.0
	IOLMaster 700				**Lenstar LS 900**			
	n	Mean (SD)	Median	Min, Max	n	Mean (SD)	Median	Min, Max
Biometry mode								
LT [mm]	112	4.643 (0.411)	4.665	3.70, 5.60	112	4.623 (0.417)	4.630	3.70, 5.62
CCT [µm]	112	549.27 (36.368)	548.5	430, 655	112	549.15 (35.411)	550.0	435, 653
The value "-2°" for Minimum axis of the IOLMaster 500 is due to the performed conversion for comparison.								

Table 2: Descriptive Statistics Summary - Difference between IOLMaster 700 and Comparison Devices

Difference between IOLMaster 700 and IOLMaster 500					
	N	Mean (SD)	Median	Min, Max	p-value T-test for paired samples
Biometry mode					
AL [mm]	113	0.004 (0.025)	0.000	-0.06, 0.09	0.074
ACD [mm]	113	0.017 (0.121)	-0.010	-0.30, 0.38	0.149
Keratometry mode					
R1, Radius in Flat Meridian [mm]	113	0.001 (0.044)	0.000	-0.14, 0.25	0.949
R2, Radius in Steep Meridian [mm]	113	-0.002 (0.046)	0.000	-0.16, 0.13	0.598
SE [D]	113	-0.001 (0.190)	0.000	-0.92, 0.62	0.937
Cyl [D]	113	0.013 (0.318)	-0.008	-0.88, 0.87	0.659
A [°]	59	1.407 (11.388)	0	-35, 32	0.347
WTW mode					
WTW [mm]	97	-0.125 (0.167)	-0.10	-0.8, 0.4	<0.001
Difference between IOLMaster 700 and Lenstar LS 900					
	N	Mean (SD)	Median	Min, Max	p-value T-test for paired samples
Biometry mode					
LT [mm]	112	0.020 (0.120)	0.000	-0.32, 0.67	0.079
CCT [µm]	112	0.116 (4.492)	-1.0	-9, 13	0.785
The difference for each subject between the two devices = IOLMaster 700 – comparison device.					

Table 3: Mean Difference Between Devices (with Limits of Agreement)

Difference between IOLMaster 700 and IOLMaster 500						
	N	IOLMaster 700 Mean (SD)	IOLMaster 500 Mean (SD)	Difference Mean (SD) (95% CI)	Lower Limit of Agreement	Upper Limit of Agreement
Biometry mode						
AL [mm]	113	23.636 (1.820)	23.632 (1.811)	0.004 (0.025) (0.000, 0.009)	-0.045	0.053
ACD [mm]	113	3.061 (0.415)	3.044 (0.402)	0.017 (0.121) (-0.006, 0.039)	-0.221	0.254
Keratometry mode						
R1, Radius in Flat Meridian [mm]	113	7.784 (0.250)	7.783 (0.252)	0.001 (0.044) (-0.008, 0.009)	-0.086	0.087
R2, Radius in Steep Meridian [mm]	113	7.610 (0.238)	7.613 (0.238)	-0.002 (0.046) (-0.011, 0.006)	-0.093	0.088
SE [D]	113	43.175 (1.326)	43.176 (1.329)	-0.001 (0.190) (-0.037, 0.034)	-0.374	0.371
Cyl [D]	113	0.969 (0.627)	0.956 (0.663)	0.013 (0.318) (-0.046, 0.072)	-0.610	0.636
A [°]	59	90.63 (68.224)	89.22 (67.078)	1.407 (11.3883) (-1.561; 4.375)	-20.91	23.73
WTW mode						
WTW [mm]	97	11.889 (0.407)	12.024 (0.429)	-0.125 (0.167) (-0.158, -0.091)	-0.452	0.203
Difference between IOLMaster 700 and Lenstar LS 900						
	N	IOLMaster 700 Mean (SD) (95% CI)	Lenstar LS 900 Mean (SD) (95% CI)	Difference Mean (SD) (95% CI)	Lower Limit of Agreement	Upper Limit of Agreement
Biometry mode						
LT [mm]	112	4.643 (0.411)	4.623 (0.417)	0.020 (0.120) (-0.002, 0.043)	-0.246	0.256
CCT [µm]	112	549.27 (36.368)	549.15 (35.411)	0.116 (4.492) (-0.725, 0.957)	-8.688	8.920
The difference for each subject between the two devices = IOLMaster 700 – comparison device.						

Additionally, analysis of variance (ANOVA) with random effect models was used to evaluate the repeatability and reproducibility of each measurement parameter for the IOLMaster 700. Table 4 below summarizes the standard deviation and percent coefficient of variation for ANOVA components due to repeated measurements, different devices or study site, and the total of these two components. It should be noted that the information for operator effect was not collected.

Table 4: IOLMaster 700 Variation Components

Parameter	N	Mean	Between-Replicates (SD, %CV)		Between-Site/Device (SD, %CV)		Total (Overall) (SD, %CV)	
Biometry mode								
AL [mm]	117	23.605	0.009	0.037%	0.318	1.346%	0.318	1.346%
ACD [mm]	117	3.053	0.010	0.314%	0.057	1.853%	0.057	1.879%
CCT [µm]	117	548.598	2.271	0.414%	2.844	0.518%	3.640	0.663%
LT [mm]	117	4.661	0.019	0.410%	0.000	0.000%	0.019	0.410%
Keratometry mode								
R1 [mm]	109	7.784	0.026	0.334%	0.032	0.411%	0.041	0.530%
R2 [mm]	109	7.617	0.024	0.316%	0.044	0.580%	0.050	0.661%
SE [D]	109	43.159	0.100	0.231%	0.232	0.537%	0.252	0.585%
Cyl [D]	109	0.934	0.191	20.449%	0.000	0.000%	0.191	20.449%
A [°]	59	81.249	5.633	6.93%	0.000	0.000%	5.633	6.93%
WTW mode								
WTW [mm]	115	11.928	0.090	0.755%	0.018	0.155%	0.092	0.771%
Axis analysis includes study eyes with corneal cylinder power > 0.75 D only.								

The table above shows the variance components for effect due to site/device and effect due to replicates and the corresponding repeatability and reproducibility as well as an overall SD and COV value.

Summary

The results of the IOLMaster 700 measurements are comparable to those of the predicate devices, IOLMaster 500 and Lenstar LS 900. In comparison with the predicate biometry devices, the IOLMaster 700 demonstrated good repeatability and reproducibility for all parameters.