APR 1 2 2013

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(a).

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

a.	Applicant:	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 07745 Jena Germany
b.	Contact Person:	Judith A. Brimacombe, MA Director, Clinical/Regulatory Affairs Carl Zeiss Meditec, Inc. 5160 Hacienda Drive Dublin, CA 94568 USA j.brimacombe@meditec.zeiss.com Tel: (925) 557-4616 Fax: (925) 557-4259
c.	Summary Prepared:	August 6, 2012

NAME OF DEVICE, INCLUDING TRADE NAME AND CLASSIFICATION NAME

a.	Trade/Proprietary Name:	IOLMaster® 500
b.	Common/Usual Name:	Biometer
c.	Classification Name:	AC-powered slit lamp biomicroscope
d.	Product Code and Class:	HJO – Class II
e.	Classification Number:	886.1850

PREDICATE DEVICE

The IOLMaster 500, the subject of this 510(k), is substantially equivalent to the predicate IOLMaster 500 (Carl Zeiss Meditec, AG) cleared for marketing under 510(k) number K101182 in October 2010.

DEVICE DESCRIPTION

The IOLMaster 500 is a non-contact biometry instrument for measurements of the eye required for preoperative computation of intraocular lens (IOL) type and power. As with the IOLMaster 500 predicate device, the IOLMaster 500 provides measurements of axial length, corneal radius (keratometry), anterior chamber depth and the "white-to-white" distance (WTW).

STATEMENT OF INTENDED USE

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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The IOLMaster 500 has the same indications for use and operating characteristics as the predicate IOLMaster 500.

The IOLMaster 500 utilizes partial coherence interferometry and traditional ophthalmic biometry techniques to obtain measurements for axial length, corneal radius, anterior chamber depth and white-to white distance. Integrated algorithms in the software allow for the use of clinically recognized formulas for the calculation of IOL type and power prior to cataract surgery. These functions are identical for the IOLMaster 500 and the predicate device.

New software features have been added to the updated IOLMaster 500. These include implementation of the Holladay 2 IOL calculation formula, improvements in displayed parameters, and the use of Netviewer one2meet for remote connection to Carl Zeiss Meditec Service.

As the measurements are achieved in the same manner using the identical optical technology, the IOLMaster 500 is therefore substantially equivalent to the predicate IOLMaster 500 (K101182).

BRIEF SUMMARY OF PERFORMANCE TESTS AND RESULTS

A prospective, single site clinical study comparing the performance of the IOLMaster 500 with the Marco (Bausch & Lomb, Inc.) manual keratometer was conducted in 61 astigmatic eyes with at least 0.75 D of astigmatism. This study evaluated the agreement in the keratometry function for corneal power, cylindrical power (i.e., astigmatic power) and axis. The agreement between the instruments is summarized in Table 1.

TABLE 1
AGREEMENT BETWEEN THE MARCO KERATOMETER AND THE IOLMASTER IN 61 EYES (ALL VALUES ARE IN D AND ARE MEAN ± SD UNLESS INDICATED)

	Marco Keratometer	IOLMaster	Difference	95% LoA
Power in Flat Meridian	42.30 ± 1.42	42.54 ± 1.40	+0.24 ± 0.13	–0.07 to +0.55
Power in Steep Meridian	43.68 ± 1.46	44.11 ± 1.47	+0.43 ± 0.21	+0.02 to +0.84
Mean Power (P1+P2)/2	42.99 ± 1.39	43.33 ± 1.37	+0.33 ± 0.13	+0.05 to +0.63
Astigmatic Power	–1.38 ± 0.80	–1.56 ± 0.86	–0.18 ± 0.23	–0.64 to +0.26
Axis [°]*	110.89 ± 71.59	113.97 ± 72.33	4.00 ± 3.30	+10.47

*The upper limit was derived based on the method of Brand and Altman (Bland, JM and Altman, DG. Statistical methods for assessing agreement between two methods of clinical measurement, Lancet, i:307-310, 1986). The lower limit was not provided since the difference in axis is always a positive number.

The results of the study demonstrate a high level of agreement between the instruments for measurements of power in the flat and steep meridians, mean power, astigmatic power and axis. Typically, the manual keratometer measured significantly flatter radii and hence lower corneal power in both meridians. The mean power (±SD) as measured by the IOLMaster was 43.33 ± 1.37 D compared to 42.99 ± 1.39 D for the manual keratometer. Overall, the manual keratometer measured less astigmatic power (-1.38 ± 0.80 D) compared to the IOLMaster (-1.56 ± 0.86 D). The differences between the measurements would be inconsequential in toric IOL calculations.

To evaluate the repeatability and reproducibility of the IOLMaster compared to the manual keratometer, the study was conducted in two phases designed to evaluate repeatability and reproducibility of the measurements.

- In Phase 1, inter-instrument variability for both the IOLMaster and the Marco keratometer was evaluated, as was the agreement between the two instruments. Three IOLMaster units and three manual keratometer units were used, and 5 measurements were taken with each unit (30 total measurements per subject).
- In Phase 2, inter-operator variability for both the IOLMaster and the Marco keratometer was evaluated, as was the agreement between the IOLMaster and the Marco keratometer. One IOLMaster unit and one Marco manual keratometer unit were used by three operators, and 5 measurements were taken by each operator (30 total measurements per subject).

The results of the analysis for repeatability and reproducibility for the Marco manual Keratometer and the IOLMaster 500 are summarized in Table 2.

TABLE 2
REPEATABILITY AND REPRODUCIBILITY
MARCO MANUAL KERATOMETER AND IOLMASTER 500

	Overall	Repeatability			Reproducibility		
	Mean	SD	Limit	%COV	SD	Limit	%COV
MARCO							
R1, Radius in Flattest Meridian [mm]	7.88	0.0381	0.1068	0.48%	0.0492	0.1376	0.62%
R2, Radius in Steepest Meridian [mm]	7.63	0.0654	0.1832	0.86%	0.0799	0.2237	1.05%
P1, Power in Flattest Meridian [D]	42.30	0.2201	0.6162	0.52%	0.2800	0.7840	0.66%
P2, Power in Steepest Meridian [D]	43.68	0.3953	1.1067	0.90%	0.4774	1.3367	1.09%
Mean Power, (P1 + P2)/2 [D]	42.99	0.2388	0.6686	0.56%	0.3162	0.8854	0.74%
Astigmatic Power [D]	-1.38	0.4249	1.1896	30.76%	0.4604	1.2890	33.34%
Axis [°]	110.89	3.1692	8.8738	2.86%	4.6560	13.0369	4.20%
IOLMaster							
R1, Radius in Flattest Meridian [mm]	7.84	0.0154	0.0431	0.20%	0.0165	0.0462	0.21%
R2, Radius in Steepest Meridian [mm]	7.56	0.0179	0.0501	0.24%	0.0192	0.0539	0.25%
P1, Power in Flattest Meridian [D]	42.54	0.0686	0.1921	0.16%	0.0748	0.2094	0.18%
P2, Power in Steepest Meridian [D]	44.11	0.0875	0.2449	0.20%	0.1010	0.2827	0.23%
Mean Power, (P1 + P2)/2 [D]	43.32	0.0563	0.1577	0.13%	0.0663	0.1855	0.15%
Astigmatic Power [D]	-1.56	0.1369	0.3833	8.75%	0.1403	0.3927	8.96%
Axis [°]	113.97	3.9249	10.9897	3.44%	4.1737	11.6863	3.66%

Repeatability includes variation due to measurement error.
Reproducibility includes variations due to device, operator, interaction between device and subject, interaction between operator and subject, and measurement error.
Repeatability %COV = (Repeatability SD)/|Overall Mean|*100%
Reproducibility %COV = (Reproducibility SD)/|Overall Mean|*100%

The prospective clinical study demonstrated excellent agreement between the IOLMaster and Marco manual keratometer for corneal power, astigmatic power and axis. As demonstrated by these results, for all measurements, with the exception of axis, the repeatability and reproducibility limits, and the standard deviations were smaller for the IOLMaster than for the manual keratometer. For axis, the instruments have similar repeatability and reproducibility.

Additionally, a retrospective analysis of a previously conducted prospective, single site clinical study comparing the performance of the IOLMaster 500 with the Javal (Haag-Streit) manual keratometer was conducted in 116 astigmatic eyes with at least 0.75 D of astigmatism. This study evaluated the agreement in the keratometry function for corneal power, cylindrical power (i.e., astigmatic power) and axis.

In this study, five measurements were taken on each eye with one IOLMaster 500 instrument and one Javal keratometer by a single operator. The agreement between the instruments is summarized in Table 3 with the repeatability of measures shown in Table 4.

TABLE 3

AGREEMENT BETWEEN THE JAVAL KERATOMETER AND THE IOLMASTER IN 116 EYES (ALL VALUES ARE IN D AND ARE MEAN ± SD UNLESS INDICATED)

	Javal Keratometer	IOLMaster	Difference	95% LoA
Power in Flat Meridian	42.02 ± 1.30	42.27 ± 1.28	+0.24 ± 0.16	–0.00 to +0.48
Power in Steep Meridian	43.31 ± 1.47	43.56 ± 1.45	+0.25 ± 0.17	–0.08 to +0.58
Mean Power (P1+P2)/2	42.67 ± 1.36	42.91 ± 1.34	+0.24 ± 0.11	+0.02 to +0.46
Astigmatic Power	–1.29 ± 0.54	–1.29 ± 0.54	–0.01 ± 0.19	–0.38 to +0.36
Axis [°]*	102.12 ± 82.19	100.63 ± 82.31	3.82 ± 3.51	+10.70

*The upper limit was derived based on the method of Brand and Altman (Bland, JM and Altman, DG. Statistical methods for assessing agreement between two methods of clinical measurement, Lancet, i:307-310, 1986). The lower limit was not provided since the difference in axis is always a positive number.

TABLE 4

REPEATABILITY OF JAVAL MANUAL KERATOMETER AND IOLMASTER 500

	Overall Mean	Repeatability		
		SD	Limit	%COV
Javal				
R1, Radius in Flattest Meridian [mm]	7.91	0.0207	0.0581	0.26%
R2, Radius in Steepest Meridian [mm]	7.67	0.0252	0.0706	0.33%
P1, Power in Flattest Meridian [D]	42.02	0.1104	0.3091	0.26%
P2, Power in Steepest Meridian [D]	43.31	0.1387	0.3885	0.32%
Mean Power, (P1 + P2)/2 [D]	42.67	0.0919	0.2574	0.22%
Astigmatic Power [D]	-1.29	0.1709	0.4787	13.27%
Axis [°]	103.67	2.8377	7.9456	2.74%
IOLMaster				
R1, Radius in Flattest Meridian [mm]	7.86	0.0109	0.0304	0.14%
R2, Radius in Steepest Meridian [mm]	7.63	0.0180	0.0503	0.24%
P1, Power in Flattest Meridian [D]	42.27	0.0587	0.1644	0.14%
P2, Power in Steepest Meridian [D]	43.56	0.1023	0.2864	0.23%
Mean Power, (P1 + P2)/2 [D]	42.91	0.0583	0.1632	0.14%
Astigmatic Power [D]	-1.29	0.1192	0.3337	9.22%
Axis [°]	102.18	2.4242	6.7877	2.37%

Repeatability includes variation due to measurement error.
Repeatability %COV = (Repeatability SD)/|Overall Mean|*100%

CONCLUSION

The IOLMaster 500 is substantially equivalent to the predicate device. Additionally, the keratometry function of the IOLMaster 500 provides cylindrical power and axis measurements comparable to manual keratometry, suitable for use in toric lens power calculations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 12, 2013

Carl Zeiss Meditec AG
% Judith A. Brimacombe, M.A.
Director, Clinical/ Regulatory Affairs
5160 Hacienda Drive
Dublin, CA 94568

Re: K122418
Trade/Device Name: IOLMaster 500
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slit lamp biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: March 12, 2013
Received: March 13, 2013

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 contact 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. 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,

Deborah L. Falls -S

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

Enclosure

Indications for Use

510(k) Number (if known): K122418

Device Name: IOLMaster 500

Indications For Use:

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 use dunder the supervision of a physician.

Prescription Use___X____ AND/OR Over-The-Counter Use_____
(part 21 CFR 801 Subpart D) (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)

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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose, and Throat Devices
510(k) Number: K122418