K101182

4.0 510(K) SUMMARY

NOV - 3 2010

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

4.1 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:	October 7, 2010

4.2 NAME OF DEVICE, INCLUDING TRADE NAME AND CLASSIFICATION NAME

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

4.3 PREDICATE DEVICE

The IOLMaster 500, the subject of this 510(k), is substantially equivalent to the predicate IOLMaster (Carl Zeiss Meditec, AG) cleared for marketing under 510(k) number K993357 and the Lenstar Model LS 900 (Haag-Streit AG) cleared for marketing under 510(k) number K082891.

4.4 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 predicate device, the IOLMaster 500 provides measurements of axial length, corneal radius (keratometry), and anterior chamber depth. In the new model of the IOLMaster, the optical measurement technology has remained the same and the measurements of axial length, corneal radius and anterior chamber depth are achieved in the same fashion. In addition to these three parameters, using the same optical techniques with advances in software, the modified IOLMaster also has the capability to measure a fourth parameter, i.e., the "white-to-white" distance (WTW). Incorporation of this additional information extends the physician's choice of computational formulas.

4.5 STATEMENT OF INTENDED USE

The IOLMaster is intended for the biometric determination of ocular measurements for 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.

4.6 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The IOLMaster 500 has the same indications for use and operating characteristics as the predicate IOLMaster with the exception that the white-to-white measurement has been added to the indications for use statement.

The IOLMaster 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 the same for the IOLMaster 500 and the predicate device.

Software enhancements using the Windows XP platform have improved the Graphic User Interface (GUI) and the usability of the IOLMaster. Additionally, modifications have been made to the IOLMaster computer hardware to incorporate USB ports for importing and exporting data to and from the IOLMaster 500.

Since the measurements are achieved in the same fashion using the identical optical technology, the IOLMaster 500 is therefore substantially equivalent to the predicate IOLMaster (K993357).

4.7 CLINICAL EVALUATION

Clinical data reported in the literature was reviewed to determine agreement between the IOL Master, Grieshaber Biometric System, and Lenstar Model LS900. The results are provided in Table 1 on the following page.

Axial length, anterior chamber depth and corneal radius

IOLMaster axial length (AL) and anterior chamber depth (ACD) measurements were compared to measurements obtained with a high precision immersion ultrasound system (Grieshaber Biometric System (GBS)). A total of 189 consecutive eyes presented for cataract evaluation were measured with the IOLMaster. Excluded from the study were 32 eyes not measured with GBS. Mean difference for axial length was calculated based on 146 phakic eyes comparative axial length measurements between IOLMaster and GBS (10 pseudophakic eyes and 1 aphakic eye were excluded). Mean difference for ACD was calculated based on measurements on 151 eyes comparing IOLMaster and GBS (in 6 pseudophakic eyes, ACD could not be measured). Mean difference for the average corneal radius was calculated based on keratometry measurements on 154 eyes comparing IOLMaster and a handheld keratometer ((Renaissance, Alcon). Two eyes with no available keratometry results and one eye with unreliable readings due to dry eye were excluded).[1]

White-to-white measurement

IOLMaster white-to-white measurements were compared to measurements obtained with a Lenstar LS 900 (Haag-Streit) in 112 cataract surgery eyes.[2]

[1] Haigis W, Lege B: Akustische und optische Biometrie im klinischen Einsatz; in Wenzel M, Kohnen T, Blumer B. (eds): 14. Kongress der Deutschsprachigen Gesellschaft für Intraokularlinsen-Implantation und refractive Chirurgie, Jahresband der DGII, Luzern, February 2000. Koln, Biermann, 2000, pp 73-78.
[Haigis W, Lege B: Acoustical and Optical Biometry in Clinical Application; in Wenzel M, Kohnen T, Blumer B. (eds): 14. Congress of the german-speaking society for implantation of intraocular lenses and refractive surgery (DGII), Annual book of the DGII, Luzern, February 2000. Koln, Biermann, 2000, pp 73-78.]
[2] Buckhurst PJ, Wolffson JS, Shah S, Naroo SA, Davies LN, Berrow EJ. A new optical low coherence reflectometry device for ocular biometry in cataract patients. Br J Ophthalmol 2009; 93 (7): 949-953.

Table 1. Agreement with Other Instruments

	N	Mean Difference	Standard Deviation
Axial length*	146	-0.01 mm	±0.19 mm
Corneal curvature**	154	-0.01 mm	±0.05 mm
Anterior chamber depth*	151	+ 0.03 mm	±0.18 mm
White-to-white***	112	+ 0.06 mm	±0.33 mm

All referenced studies compared measurements from eyes evaluated for cataract surgery.

* In comparison to high precision immersion ultrasound instrument (Grieshaber Biometric Systems, GBS)[1]
** In comparison to manual keratometer (Renaissance, Alcon)[1]
*** In comparison to optical low coherence reflectometry (Lenstar LS900, Haig-Streit)[2]

Repeatability and Reproducibility

A study[3] was conducted to determine repeatability and reproducibility of the IOLMaster 500 measurements of axial length (AL), corneal radius (corneal curvature), anterior chamber depth (ACD) and white-to-white (WTW). Phase I of the study enrolled 30 subjects and was designed to determine inter-device variability, wherein each subject was imaged 3 times during a single visit on each of three IOLMaster 500 instruments by one operator. Phase II enrolled the same 30 subjects and was designed to determine inter-operator variability, wherein each subject was imaged three times during a single visit by each of three operators. Subjects in the study were 18 years or older with healthy eyes and no ocular opacities. The precision of axial length measurements and anterior chamber depth measurements may be different in eyes with cataract or corneal abnormalities.

The repeatability and reproducibility results are shown in Table 2 on the following page.

[3]Carl Zeiss Meditec, Inc., Clinical Study: Repeatability and Reproducibility of IOLMaster 500; 2010.

Table 2. Repeatability and Reproducibility of the IOLMaster 500 Measurements

	Repeatability		Reproducibility	
	Repeatability SD (mm)	Repeatability Limit (mm)	Reproducibility SD (mm)	Reproducibility Limit (mm)
Axial length	0.0206	0.0577	0.0222	0.0623
Corneal curvature	0.0162	0.0455	0.0167	0.0468
Anterior chamber depth	0.0347	0.0972	0.0494	0.1383
White-to-white	0.0558	0.1562	0.0647	0.1811

Repeatability is defined as the standard deviation of measurements taken by a single operator/single instrument. The repeatability standard deviation was estimated by the square root of mean squared error.
Reproducibility is the standard deviation of measurements that include between operator and between instrument variability. The reproducibility standard deviation was estimated by the square root of the sum of random measurement variability, inter-device variability, inter-operator variability, subject and device interaction variability, and subject and operator interaction variability.
The repeatability limit is the upper 95% limit for the differences between repeated results. Per ISO 5725-6, the repeatability limit = 2.8 x repeatability SD.
The reproducibility limit is the upper 95% limit calculated for the difference between individual measurements using different operators and different instruments. Per ISO 5725-6, the reproducibility limit = 2.8 x the reproducibility SD.

4.8 Brief Summary of Performance Tests and Results

The IOLMaster has been designed and tested to the applicable safety standards. The performance data supporting safety and substantial equivalence of the IOLMaster 500 to the predicate device demonstrates that:

- the axial length, corneal radius, anterior chamber depth measurements of the modified IOLMaster are substantially equivalent to those of the predicate device;
- white-to-white measurements using the IOLMaster 500 are substantially equivalent to those of the predicate device;
- the IOLMaster meets the requirements for electrical and laser safety;
- usability of the IOLMaster has been verified in accordance with appropriate standards.

4.9 Conclusion

The IOLMaster 500 is substantially equivalent to the predicate devices.

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

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

NOV - 3 2010

Re: K101182
Trade Name: IOLMaster 500
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slit lamp biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: September 13, 2010
Received: September 14, 2010

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,

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

INDICATIONS FOR USE

510(k) Number (if known): K101182

Device Name(s): IOLMaster 500

NOV - 3 2010

Indications for Use:

The IOLMaster is intended for the biometric determination of ocular measurements for 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.

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)

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

510(k) Number K101182