

MAR 20 2000



510(k) Summary

K993357

Pursuant to 21 CFR 807.92 the following summary is submitted.

1. **Submitter's Name** Carl Zeiss, Inc.  
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Thornwood, NY 10594  
**Telephone** (914) 681 7880  
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**Contact Person** Scott A. Margolin  
Regulatory Affairs Specialist  
  
**Date Submitted** October 4, 1999
2. **Trade Name** IOLMaster  
**Proposed Classification Name** Keratoscope: § 886.1350  
AC-Powered slitlamp  
biomicroscope: 886.1850
3. We are claiming substantial equivalence to the technology of the Humphrey Systems OCT (K961171) and the technology and indications of the Zeiss SL 120 slit lamp (K925641) and the indications of the Quantel Medical B-Scan 'S' Model (K926251), for determining axial eye length measurement and anterior chamber depth measurement, and the Humphrey Auto Keratometer Model 420 (K781994) for corneal radius measurement, which already have pre-market clearance for the indications of providing measurements and generating data on axial eye length, anterior chamber depth and corneal radius, and also for performing calculations and providing the suggestions to physicians for determining the power and type of IOL (intra ocular lens) for implantation. Please see also item 7 with regard to functional and performance equivalent predicate devices for the IOLMaster.

4. The IOLMaster is a non-invasive, non-contact system for measuring the parameters of the human eye required to determine the appropriate power of IOL for implantation, (axial eye length, anterior chamber depth, and corneal radius), and for calculating the optimal power of IOL.

*Axial eye length* is measured using the principle of partial coherence interferometry (also referred to as laser Doppler interferometry), with a Michelson interferometer.

*Corneal radius* is measured using traditional keratometry principles, whereby light from LEDs is projected on the cornea of the eye, and after image capturing of the reflected marks and image processing provides the measurement.

*Anterior chamber depth* is measured by slit lamp illumination. The slit light is scattered by the cornea and the eye lens, generating an image of the cornea and the lens. The image is captured by a CCD-camera. Image processing and edge detection algorithms allow for calculation of the distance between the anterior surface of cornea and lens (=anterior chamber depth).

These three measurements provide the physician with the data required to calculate the power of IOL to use for a patient. The physician can then choose from one of up to five internationally accepted formulas, built into the IOLMaster, to perform the calculation. The IOL power is then calculated according to the IOL type.

Users can also enter information regarding the different IOL types into the IOLMaster database, which can then be used to suggest the optimal IOL. This calculation and selection process is already performed by ultrasound and other diagnostic devices. However, the choice of formula and final determination of the appropriate IOL is at the physicians' discretion.

The other concerns for safety are the light output and electrical safety. The device design assures that the light outputs are of an eyesafe intensity and wavelength, in compliance with both national and international safety standards. The device is designed to comply with both national and international electrical safety standards.

5. This device will be used in the same manner as all ophthalmic diagnostic devices used to obtain measurements and perform calculations for physicians to determine IOL power and type selections for a patient.
6. The IOLMaster and the predicate devices are substantially equivalent because they use similar technology and perform similar functions, to provide the ocular measurements and to perform calculations needed to allow a physician to choose the appropriate power and type of IOL for a patient.

The IOLMaster and the Humphrey Systems OCT (K961171) both use Michelson, partial coherence interferometry to obtain data regarding the eye. Both devices use a CCD Camera to capture the information. The IOLMaster enhances the imaging functions of the OCT with additional processing capabilities, allowing for the axial length measurement. The safety and efficacy of Michelson interferometry is well established.

The axial length measurement obtained through Michelson interferometry is equivalent to the information that would be obtained using a standard ultrasound scan, such as the Quantel Medical B Scan 'S' (K926251). Unlike the ultrasound device, the IOLMaster does not require contact with the eye to perform this measurement. Because there is no contact, patient safety and comfort are enhanced, as there is a reduced risk of infection and no need for local anesthetization.

The IOLMaster and the B-Scan 'S' are also similar in that both devices allow the physician to calculate the power of IOL using industry standard formulas incorporated into the processors of the devices. Both devices can also use the calculated measurements to suggest types of IOLs.

The IOLMaster is similar to the Zeiss SL 120 slit lamp / biomicroscope (K 925641) because both use traditional slit lamp principles to obtain anterior chamber depth measurements. The eye is illuminated through a slit using LED's under a fixed angle from the side. Light scattered by the cornea and lens generates a slit image. In the SL 120, an anterior chamber depth accessory and eyepiece present that information against a scale. The information from the scale is interpreted through a chart and the anterior chamber depth is determined. In the IOLMaster, the slit image is projected onto a CCD-camera and using image processing, the anterior chamber depth can be calculated. It should also be noted that anterior

chamber depth measurement can also be obtained using the ultrasound predicate device.

The IOLMaster and the Humphrey 420 auto-keratometer (K781994) both obtain corneal radius measurement using traditional keratometry techniques. The principle radius of corneal curvature is determined by shining collimated beams of light, generated by LEDs, onto the cornea and analyzing the position of the reflections using electronic image processing. Both products also allow the physician to use the measurements to calculate IOL power. However, the Humphrey 420 required the use of an ultrasound device to perform this calculation, whereas the IOLMaster performs this function independently.

The basic functionality and indications of the IOLMaster and the predicate devices are virtually identical. The IOLMaster and the predicate devices use similar technologies, functional features and indications. These devices present the same questions of safety and effectiveness. Any differences between the IOLMaster and the predicate devices do not affect the safety or effectiveness of the device.

7. The IOLMaster-prototype, as per the second stage validation and verification program, was tested in February 1999 at the University Eye Clinic, Wuerzburg, Germany. The prototype tested was equivalent in its optical, electronic and mechanical design to the production model IOLMaster, with functions for Axial Length, Corneal Radius and Anterior Chamber Depth. Software was modified to improve user convenience.

The testing served as part of the second stage validation and verification program for the IOLMaster, and followed first stage testing of 678 human eyes where it was compared against the Grieshaber Biometry System ("GBS"), a high-accuracy ultrasound biometry unit, in immersion technique, as well as the TOMEY "AL-1000" A-scan device and the ALCON "Ocuscan" keratometer.

The results of this second stage testing are set forth in a study entitled "First experiences with a New Optical Biometry Device", by Professors B.A.M. Lege, and W. Haigis.

An additional 155 human eyes were measured with the IOLMaster. The GBS, AL-1000 and the OcuScan were used as comparative devices.

The deviation of the measurement result to the corresponding comparative devices performs as follow:

- Axial Length:  $-0.03 \pm 0.21$  mm (GBS);
- Corneal Radii:  $-0.01 \pm 0.06$  mm (ALCON);
- Anterior Chamber Depth:  $0.12 \pm 0.18$  mm (GBS).

Abstract: "First Experiences with a New Optical Biometry System", by  
B.A.M. Lege, W. Haigis.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
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Rockville MD 20850

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Mr. Scott Margolin  
Carl Zeiss, Inc.  
One Zeiss Drive  
Thornwood, NY 10594

Re: K993357  
Trade Name: IOLMaster  
Regulatory Class: II  
Product Code: 21 CFR 886.1850  
Procode: 86 HJO  
Dated: January 23, 2000  
Received: January 27, 2000

Dear Mr. Margolin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K993357

Device Name: IOLMaster ophthalmic diagnostic device

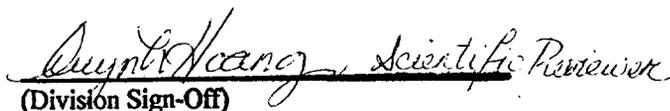
Indications For Use:

This device will be used in the same manner as all ophthalmic diagnostic devices used to obtain ocular measurements (for axial length, anterior chamber depth and corneal radius), and perform calculations to allow physicians to determine appropriate IOL power and type for implantation.

This device is intended for use primarily by physicians and health care workers and may only be used under the supervision of a physician. This device will not be sold to the general public.

(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 Devices

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