

K062930

510(k) Summary  
LADARWave® CustomCornea® Wavefront System

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Alcon Research Ltd., on behalf of  
Alcon RefractiveHorizons  
2501 Discovery Drive, Suite 500  
Orlando, FL 32826

NOV - 8 2006

A. Contact Person:

Janet G. Johnson  
Senior Manager Regulatory Affairs  
Telephone (407) 513-8954  
Fax (407) 513-7855  
Date Summary was Prepared: September 27, 2006

B. Device Information:

Proprietary Name:	LADARWave® CustomCornea® Wavefront System
Common Name:	Abberrometer, Ophthalmic
Classification Name and Regulatory Class:	Ophthalmic Refractometer 21 CFR 886.7160 Class I
Product Code:	NCF

C. Substantial Equivalence Device (Predicate):

LADARWave® CustomCornea® Wavefront System (K023249)

D. Indications for Use:

The LADARWave® CustomCornea® Wavefront System is used for measuring, recording, and analyzing visual aberrations (such as myopia, hyperopia, astigmatism, coma and spherical aberration) and for displaying refractive error maps of the eye to assist in prescribing refractive corrections.

This device is enabled to export wavefront data and associated anatomical registration information to a compatible treatment laser where a wavefront-guided treatment is indicated.

This device can also export centration data and associated registration information for conventional phoropter-based refractive surgery with the LADAR6000™ System.

E. Device Description:

The LADARWave® CustomCornea® Wavefront System is an aberrometer, utilizing Hartmann-shack wavefront sensing to measure the aberrations in the human eye. The device contains four major optical subsystems used in the clinical wavefront examination.

- A fixation subsystem provides the patient with an unambiguous point of fixation. Optics in this path automatically adjusts to correct for the patient's spherocylindrical error so that the target is clearly observed.

- A video subsystem provides the device operator with a view of the eye at the measurement plane. The operator uses the video imagery to position the eye for the measurement and to record the geometry of the wavefront relative to anatomical features.
- A probe beam subsystem directs a narrow beam of eye-safe infrared radiation into the eye to generate the re-emitted wavefront.
- A wavefront detection subsystem images the re-emitted wavefront onto the entrance face of the Hartmann-shack wavefront sensor.

These subsystems are all under control of the device software.

Once the wavefront examination is complete, the operator may export the exam data to removable media. The exported electronic file contains all information necessary to perform customized ablative surgery using either the LADARVision®4000 or LADAR6000™ System. The information includes the wavefront measurement, essential patient identification information, and geometric registration data. The electronic file is in a proprietary format and is encrypted so that wavefront data cannot be exported for use by an incompatible treatment device.

F. Substantial Equivalence Comparison:

The LADARWave® CustomCornea® Wavefront System with Assisted Registration has the same indications for use, intended use, and same technological characteristics (i.e., design, material, chemical composition, energy source) as the current LADARWave® CustomCornea® Wavefront System.

The LADARWave® CustomCornea® Wavefront System with Assisted Registration software has automated the registration process, allows the option for LADARWave wavefront measurements (pre-op) to be performed on an alternate day than the surgery, and allows centration data and associated registration data, for conventional surgery, to be performed on the LADARWave and exported to the LADAR6000™ System.

G. Testing:

Eye images were collected to perform equivalence testing of the new automated registration process. For each eye, one LADARWave wavefront session (centration photo and five wavefront measurements with associated photos) with eye marks and a session without eye marks were taken for the testing. These images were compared using the current manual "Sputnik" method and the "Overlay" assisted registration method. The primary test was to establish equivalence of the two methods of registration by testing that the accuracy in translational (x,y) and cyclotorsional registration for the "overlay" method are at least as good as with the current "sputnik" method.

The results demonstrate that the "overlay" method is as good or better than the "sputnik" method in offset registration and rotational registration at all values of registration error (i.e. at all x-axis values).

Additionally, system level software verification and validation were successfully completed in accordance with *General Principles of Software Validation; Final Guidance for Industry and FDA Staff* dated January 11, 2002.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Alcon Research, Ltd.  
c/o Ms. Janet G Johnson  
Senior Manager, Regulatory Affairs  
2501 Discovery Drive, Suite 500  
Orlando, FL 32826

NOV - 8 2006

Re: K062930

Trade/Device Name: LADARWave<sup>®</sup> CustomCornea<sup>®</sup> Wavefront System  
Regulation Number: 21 CFR 886.1760  
Regulation Name: Ophthalmic Refractometer  
Regulatory Class: I  
Product Code: NCF  
Dated: September 27, 2006  
Received: September 28, 2006

Dear Ms. Johnson:

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.

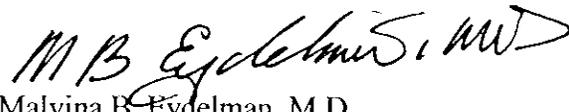
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

510(k) Number (if known): K062930  
Device Name: Alcon LADARWave<sup>®</sup> CustomCornea<sup>®</sup> Wavefront System

**Indications for Use Statement**

The LADARWave<sup>®</sup> CustomCornea<sup>®</sup> Wavefront System is used for measuring, recording, and analyzing visual aberrations (such as myopia, hyperopia, astigmatism, coma and spherical aberration) and for displaying refractive error maps of the eye to assist in prescribing refractive corrections.

This device is enabled to export wavefront data and associated anatomical registration information to a compatible treatment laser where a wavefront-guided treatment is indicated.

This device can also export centration data and associated registration information for conventional phoropter-based refractive surgery with the LADAR6000<sup>™</sup> System.

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

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

*David L. Kowalski*

(Division Sign-Off)

Division of Ophthalmic Ear,  
Nose and Throat Devices

510(k) Number K062930

Prescription Use: X Or Over the Counter Use: \_\_\_\_\_  
(Per 21 CFR 801.109)