510 (k): K100253

510(K) SUMMARY

JUL - 8 2010

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:
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c. Date Prepared: April 28, 2010

NAME OF DEVICE, INCLUDING TRADE NAME AND CLASSIFICATION NAME

a. Trade/Proprietary Name: VisuMax Laser Keratome

b. Common/Usual Name: VisuMax Laser Keratome

c. Classification Name: Laser Instrument, Surgical, Powered Keratome, AC-powered

d. Classification Code(s): 21 CFR 886.4390; 79 HFQ
21 CFR 886.4310; 79 HNO

PREDICATE DEVICES FOR THE VISUMAX LASER KERATOME

PREDICATE DEVICE	MANUFACTURER	510(K) CLEARANCE NUMBER	CLEARANCE DATE
HORUS Laser Keratome	Carl Zeiss Meditec	K062314	December 22, 2006
IntraLase FS Laser	Abbott Medical Optics	K041893	July 29, 2005

DEVICE DESCRIPTION

The VisuMax Laser Keratome is an ophthalmic surgical femtosecond laser intended for use in patients requiring corneal incisions. The cutting action of the VisuMax Laser Keratome is achieved through precise individual micro-photodisruptions of tissue, created by tightly focused ultrashort pulses which are delivered through a disposable applanation lens while fixating the eye under very low vacuum.

STATEMENT OF INTENDED USE

The VisuMax Laser Keratome is indicated for the following:

- In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea;
- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea;
- In the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty;
- In the creation of a cut/incision for penetrating keratoplasty and corneal harvesting.

TECHNOLOGICAL CHARACTERISTICS COMPARISON

The VisuMax Laser Keratome laser is substantially equivalent to the HORUS Laser Keratome also by Carl Zeiss Meditec (K062314), as well as the IntraLase FS Laser (K041893) by Abbott Medical Optics.

The VisuMax Laser Keratome has the same operating characteristics as the predicate devices, the HORUS (5062314), and the IntraLase FS Lasers (K993153, K001211, K002890, K013941, K031960, K041893, K060372, K063682, and K073404). Therefore, the VisuMax Laser Keratome is substantially equivalent to these legally marketed predicate devices.

SUMMARY OR PROPOSED MODIFICATIONS INCLUDED IN THIS 510(K) PREMARKET NOTIFICATION

The subject of this traditional premarket notification 510(k) is the expansion of the indications for use of the predicate device (HORUS Laser Keratome) to include lamellar keratoplasty and penetrating keratoplasty, consistent with the indication for use of the predicate device for other commercially available femtosecond lasers. The indications for use for the VisuMax Laser Keratome would be the same as those for the predicate device (the IntraLase FS Laser).

Additionally, modifications have been introduced to the device hardware and software specifications in order to allow for the addition of the lamellar and penetrating keratoplasty capability and to enhance the laser's usability in the clinic setting.

These modifications include:

- An increase in pulse repetition rate from 200 kHz to 500 kHz to allow the femtosecond resections and/or incisions to be performed with acceptable procedure times
- An increase in the maximum average laser power as a result of the higher pulse repetition rate, however the total laser energy delivered to the eye is unchanged
- Reduction of the maximum laser pulse peak power and the therapy pulse energy
- The addition of a trackball and touch screen to the GUI
- Improved ergonomics of the Patient Supporting System and to the laser housing to facilitate the ease of use
- An additional slit projector to facilitate better patient handling
- An additional IR light source to improve illumination of the surgical field

BRIEF SUMMARY OF PRE-CLINICAL AND CLINICAL PERFORMANCE TESTING

The VisuMax Laser keratome has been designed and tested to applicable safety standards. The performance data supporting safety and substantial equivalence of the VisuMax Laser Keratome to the predicate devices are summarized as follows:

- *Ex-vivo* porcine eye studies demonstrate the accuracy and reproducibility of the VisuMax Laser Keratome for lamellar keratoplasty incisions and that the level of precision is maintained over a wide range of incision diameters and depths. The results further demonstrate that the proposed device performed equivalently to the predicate device.
- *Ex-vivo* study in human globes shows that the quality of the full penetrating keratoplasy performance of the VisuMax Laser Keratome and the predicate device are comparable.

CONCLUSION

The VisuMax Laser Keratome 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 AG
c/o Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories, Inc.
333 Pfinsten Road
Northbrook, IL 60062

JUL - 8 2010

Re: K100253
Trade/Device Name: VisuMax Laser Keratome
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: II
Product Codes: HQF, HNO
Dated: June 22, 2010
Received: June 23, 2010

Dear Mr. Devine:

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 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,

for Lesia Alexander

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

510(k) Number (if known): K100253

Device Name(s): VisuMax Laser Keratome

Indications for Use:

The VisuMax Laser Keratome is indicated for the following:

- In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea;
- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea;
- In the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty;
- In the creation of a cut/incision for penetrating keratoplasty and corneal harvesting.

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

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