

*K101006*

**5. 510(K) SUMMARY**

**510(k) Summary**

This summary document is being prepared in accordance with section 21 CFR 807.92(c).

The submitter of the 510(k) is:

Michael Buenger  
Associate Director, Regulatory Affairs  
Alcon Research, Ltd.  
6201 South Freeway  
Fort Worth, TX 76134  
Phone: (817) 551-6810  
Fax: (817) 551-4630

Date Summary Revised: September 30, 2010

Device Subject to this 510(k):

Trade Name: WaveLight® FS200 Laser System  
Common Name: Laser  
Classification Name: Powered Laser Surgical Instrument

**1. Predicate Devices:**

The legally marketed device(s) to which we are claiming substantial equivalence are:

| <b><u>510(k) Number</u></b> | <b><u>Device</u></b>       |
|-----------------------------|----------------------------|
| K060372                     | FS Laser System            |
| K032910                     | Carriazo Pendular Keratome |
| K073404                     | iFS Laser System           |

**2. Device Description:**

The WaveLight® FS200 Laser System is a stationary scanning-spot femtosecond laser system used in refractive surgery.

## **WaveLight® FS200 Laser System**

### **3. Indications for Use:**

Indications for Use:

The WaveLight® FS200 Laser System is an ophthalmic surgical laser indicated for use:

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

### **4. Statement of how the Technological Characteristics of the Device compare to those of the Predicate or legally marketed Device**

The technological characteristics of the WaveLight® FS200 Laser System are very similar to those of the predicate laser devices. The WaveLight® FS200 Laser System and the predicate laser devices are femtosecond lasers which work in the same mode at similar frequencies with similar spot sizes. The WaveLight® FS200 Laser System works at a slightly higher pulse repetition rate and shorter pulse duration. The WaveLight® FS200 Laser System and the predicate laser devices use similar common materials and the same energy source. Therefore, the technological characteristics of the WaveLight® FS200 Laser System are substantially equivalent those of the predicate laser devices cleared under K060372 and K073404.

The technological characteristics of the WaveLight® FS200 Laser System and the Carriazo Pendular Keratome (K032910) are different in that the predicate device is a mechanical keratome. The Carriazo Pendular Keratome was used as a predicate device for the purpose of flap cutting comparison. The WaveLight® FS200 is considered as an alternative to mechanical microkeratomes.

## **WaveLight® FS200 Laser System**

### **5. Brief Summary of Nonclinical Test and Results:**

The WaveLight® FS200 Laser System has undergone testing and is in compliance with the applicable safety standards.

Performance tests according to the FDA Guidance “Keratome and Replacement Keratome Blades Premarket Notification [(510(k)) Submissions” were conducted to collect data on the accuracy, precision and quality of the cuts achieved with the WaveLight® FS200 Laser System .

The WaveLight® FS200 Laser System and the accessory Patient Interface were found to perform equivalently to the predicate laser and microkeratome and their patient interfaces for the creation of corneal cuts.



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

Alcon Research, Ltd.  
c/o Mr. Michael Buenger  
Associate Director, Regulatory Affairs  
6201 South Freeway  
Forth Worth, TX 76134

OCT 21 2010

Re: K101006

Trade/Device Name: WaveLight® FS200 Laser System  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Powered Laser Surgical Instrument  
Regulatory Class: Class II  
Product Code: GEX, HNO  
Dated: October 1, 2010  
Received: October 6, 2010

Dear Mr. Buenger:

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.

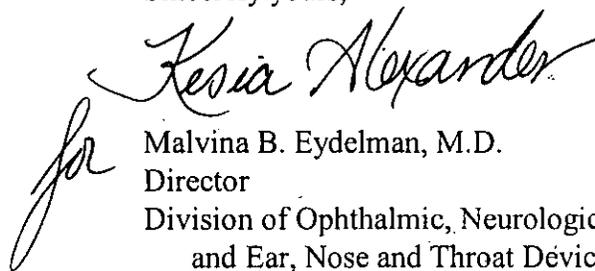
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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/ucml15809.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" (21 CFR 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,

A handwritten signature in black ink, appearing to read "Malvina B. Eydelman". The signature is written in a cursive style and is positioned to the left of the typed name and title.

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

K101006  
OCT 21 2010

WaveLight® FS200 Laser System

4. INDICATIONS FOR USE STATEMENT

510(k) Number: K101006

Device Name: WaveLight® FS200 Laser System

Indications for Use:

The WaveLight® FS200 Laser System is an ophthalmic surgical laser indicated for use:

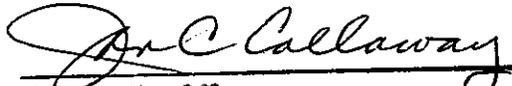
- In the creation of a corneal flap in patients undergoing LASIK surgery or other surgery or treatment requiring initial lamellar resection of the cornea.
- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal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

Prescription Use  X  AND/OR  
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use \_\_\_\_\_  
(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)

  
(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,  
Nose and Throat Devices

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