FEB 9 2007

510(K) SUMMARY

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:
IntraLase Corp.
9701 Jeronimo Road
Irvine, CA 92618
Tel: (949) 859-5230
Fax: (949) 583-9557

b. Contact Person:
Betty Johnson
IntraLase Corp.
9701 Jeronimo Road
Irvine, CA 92618
Tel: (949) 859-5230
Fax: (949) 583-9557
bjohnson@intralase.com

c. Date of Summary Preparation: February 1, 2007

NAME OF DEVICE, INCLUDING TRADE NAME AND CLASSIFICATION NAME:

Trade/Proprietary Name:	IntraLase Fusion Laser
Common/Usual Name:	Laser
Classification Name:	Keratome
Classification Code(s):	79 GEX, 86 HNO

IDENTIFICATION OF THE PREDICATE DEVICE OR LEGALLY MARKETED DEVICE OR DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS BEING CLAIMED:

510(k) #	Trade Name	Manufacturer
K060372	IntraLase FS Laser	IntraLase Corp.

A DESCRIPTION OF THE DEVICE THAT IS THE SUBJECT OF THE 510(K), INCLUDING EXPLANATION OF HOW THE DEVICE FUNCTIONS, BASIC SCIENTIFIC CONCEPTS, SIGNIFICANT PHYSICAL AND PERFORMANCE CHARACTERISTICS (DESIGN, MATERIAL, PHYSICAL PROPERTIES):

The IntraLase Fusion Laser is a precision ophthalmic surgical laser designed for use in performing lamellar corneal resections and incisions. The cutting action of the IntraLase Fusion Laser is achieved through precise individual micro-photodisruptions of tissue, created by tightly focused

ultrashort pulses which are delivered through a disposable applanation lens assembly while fixating the eye under low vacuum.

STATEMENT OF INTENDED USE:

The IntraLase Fusion™ Laser is an ophthalmic surgical laser indicated for use in the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.

STATEMENT OF HOW THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARE TO THOSE OF THE PREDICATE OR LEGALLY MARKETED DEVICE:

The technological characteristics of the IntraLase Fusion Laser have are substantially equivalent to those cleared under K060372 for lamellar corneal resections and incisions.

BRIEF SUMMARY OF NONCLINICAL TESTS AND RESULTS:

The IntraLase Fusion Laser has undergone testing and is in compliance with applicable safety standards. The IntraLase Fusion Laser and the accessory IntraLase Fusion Patient Interface were found to perform equivalently to the predicate laser and patient interface for the creation of corneal resections. Thus, the IntraLase Fusion Laser and the predicate device have similar safety, effectiveness and performance profiles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

IntraLase Corp.
c/o Judy F. Gordon, DVM
ClinReg Consulting Services, Inc.
733 Bolsana Dr.
Laguna Beach, CA 92651

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Re: K063682
Trade/Device Name: IntraLase® Fusion™ Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Codes: GEX, HNO
Dated: December 8, 2006
Received: December 11, 2006

Dear Dr. Gordon:

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

CDRH INDICATIONS FOR USE

510(k) Number (if known): K063682

Device Name(s): IntraLase Fusion™ Laser

Indications for Use:

The IntraLase Fusion™ Laser is an ophthalmic surgical laser indicated for use in the creation of corneal flaps in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.

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)

Marsha R. Burke Nicholas

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

510(k) Number K063682