5. 510(K) SUMMARY

This summary is in accordance with 21 CFR 807.92(c).

K062624

The submitter of the 510(k) is:

Terry J. Dagnon
Director, Regulatory Affairs
Alcon, Inc.
6201 South Freeway
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NOV - 5 2007

Date Prepared: August 31, 2006

Device Subject to this 510(k):

Trade Name:	Next Generation Laser
Common Name:	Ophthalmic Laser or, Frequency Doubled (532nm) Laser
Classification Name:	Laser, Ophthalmic (21 CFR 886.4390)

5.1. Predicate Devices

510(k) Number	Device
K962592	Alcon Eyelite®
K041598	Laserex™ Solitaire
K031665	Iris Medical Oculight™

5.2. Device Description

The *NGL Ophthalmic Laser,* like its predicate device Alcon *Ophthalas*® 532 *EyeLite*® (*EyeLite*®), is a diode pumped Neodymium-doped solid state laser designed for ophthalmic use. LASER is an acronym for "Light Amplification by Stimulated Emission of Radiation." This laser delivers a visible 532 nm green laser beam (frequency doubled), and a visible 635 nm Diode Laser aiming beam (635 nm is an approximate value between 630-640 nm).

The laser firing is actuated by footswitch. The laser is delivered to the patient through any of the following accessories (a) Slit Lamp, (b) Laser Probe or (c) Laser Indirect Ophthalmoscope (LIO).

In case of the *NGL,* like its predicate device Alcon *Ophthalas*® 532 *EyeLite*® (*EyeLite*®), the laser beam is generated when a laser diode beam excites the Neodymium atoms in the rod material. When one atom which has been excited by the beam returns to its initial stable level, the energy difference between the two states is emitted as radiation in the form of a photon. When this photon meets another excited atom, emission of a second photon occurs. The second photon has the same phase, wavelength, and direction as the first photon. The light emitted in this manner oscillates between two end mirrors. The light is amplified by this

stimulated emission process and a laser beam is produced. This laser beam is frequency doubled in a special crystal. The crystal is an optical dielectric that exhibits a non-linear optical response. The 532 nm wavelength is produced by harmonic generation. These steps leading to generation of the output laser beam generation is done in the laser engine module of the device.

A red 635 nm laser diode provides the visible aiming beam in NGL.

5.3. Indications for Use

The NGL is indicated for use in photocoagulation of both anterior and posterior segments of the eye including:

- Retinal Photocoagulation, panretinal photocoagulation and intravitreal endophotocoagulation of vascular and structural abnormalities of the retina and choroid including:
  - Proliferative and nonproliferative retinopathy (including diabetic);
  - Choroidal neovascularization secondary to age-related macular degeneration;
  - Retinal tears and detachments;
  - Macular Edema;
  - Retinopathy of prematurity;
  - Choroidal neovascularization;
  - Leaking microaneurysms.
- Iridotomy/Iridectomy for treatment of Chronic/Primary Open Angle Glaucoma (COAG,POAG), Acute Angle Closure Glaucoma (AACG), and Refractory Glaucoma.
- Trabeculoplasty for treatment of Chronic/Primary Open Angle Glaucoma (COAG,POAG) and Refractory Glaucoma.
- And other laser treatments including:
  - Internal sclerostomy;
  - Lattice degeneration;
  - Central and Branch Retinal Vein Occlusion;
  - Suturelysis;
  - Vascular and pigmented skin lesions.

5.4. Brief Summary of Nonclinical Tests and Results

The device will comply with applicable sections of 21 CFR 1040 and the following standards:

Standard #	Title
11135 AAMI/ISO	Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization
14971 ISO	Medical Devices: Application of Risk Management to Medical Devices
10993-1 AAMI / ANSI / ISO	Biological evaluation of medical devices -- Part 1: Evaluation and testing
10993-5 AAMI /	Biological evaluation of medical devices -- Part 5: Tests for In Vitro

Standard #	Title
ANSI / ISO	cytotoxicity
10993-7 AAMI / ANSI / ISO	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals
10993-10 AAMI / ANSI / ISO	Biological evaluation of medical devices -- Part 10: Tests for irritation and sensitization
10993-11 AAMI / ANSI / ISO	Biological Evaluation of Medical Devices - Part 11: Tests for systemic toxicity
EN 60601-1: 1990	Medical Electrical Equipment, Part 1 – General Requirements for Safety. (Including A1:1992, A2:1995 and A13:1995)
EN 60601-1-2: 2001	Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standard: Electromagnetic compatibility–Requirements and test.
EN 60601-2-22: 1996	Medical electrical equipment Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment
EN 60601-1-4:1996	Medical Electrical Equipment, Part 1: General Requirements for Safety. 4. Collateral standard: Programmable electrical medical systems. (Including A1: 1999)
UL 60601-1: 2003	Medical Electrical Equipment, Part 1 – General Requirements for Safety
IEC 60825-1:1993	Radiation safety of laser products, equipment classification, requirements and user's guide. (Including A1:1997 and A2:2001)

Technological characteristics affecting clinical performance are similar to that of predicate devices previously listed. The Next Generation Laser system will be developed and manufactured in compliance with FDA and ISO quality system requirements. Testing will demonstrate that the functional requirements have been met and that the system specifications have been met prior to commercial product release.

The NGL console is provided non-sterile, and is not intended to be sterilized.

The Laser Probes are provided sterile. They are intended for single use.

Sterilization method for the Laser Probes will be a validated EtO sterilization cycle.

The Laser Probes will utilize the same packaging concept as used previously for similar products of adhesive backed Tyvek lidding sealed to HIPS (high impact polystyrene) trays. These packs can withstand validated sterilization processes of EtO sterilization to achieve a 10^{-6} SAL (sterility assurance level).

5.5. Trademark Reference

Oculight is a registered trademark of Iris Medical
Laserex is a registered trademark of Ellex Medical Pty. Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alcon Research, Ltd.
% Terry J. Dagnon
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Fort Worth, Texas 76134

NOV - 5 2007

Re: K062624
Trade/Device Name: Next Generation Laser
Regulation Number: 21 CFR 886.4390
Regulation Name: Opthalmic laser
Regulatory Class: II
Product Code: HQF
Dated: August 15, 2007
Received: August 16, 2007

Dear Terry Dagnon:

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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS AND USE STATEMENT

510(k) Number (if known): K062624

Device Name: Next Generation Laser

Indications for Use:

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  - Suturelysis;
  - Vascular and pigmented skin lesions.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K062624