



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ellex Medical Pty Ltd
c/o Kevin Howard
Regulatory Officer
82 Gilbert Street
Adelaide, SA 5000
Australia

MAR 16 2006

Re: K052777

Trade/Device Name: Laserex Duo family of dual wavelength ophthalmic lasers. Including models Integre Duo LP1RG-S, LP1RG-D and Avante Duo LP2RG.

Regulation Number: 21 CFR 886.4390

Regulation Name: Ophthalmic laser

Regulatory Class: Class II

Product Code: HQF; GEX

Dated: December 19, 2005

Received: December 21, 2005

Dear Mr. Howard:

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 (301) 827-8910. 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "MB Eydelman, MD", with a stylized flourish at the end.

Malvina B. Eydelman, M.D.
Acting Division Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052777

Device Name: Laserex Duo family of dual wavelength ophthalmic lasers. Including models Integre Duo LP1RG-S, LP1RG-D and Avante Duo LP2RG.

Indications for Use:

The Laserex Duo family of dual wavelength ophthalmic lasers are intended for use in the treatment of ocular pathology.

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

- Retinal photocoagulation and pan retinal photocoagulation of vascular and structural abnormalities of the retina and choroid including:
 - proliferative and nonproliferative diabetic retinopathy;
 - choroidal neovascularization;
 - branch retinal vein occlusion;
 - age-related macular degeneration;
 - retinal tears and detachments;
 - retinopathy of prematurity;
- Iridotomy, iridectomy, suturelysis and trabeculoplasty in angle closure glaucoma and open angle glaucoma

Prescription Use ✓ 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)

Denis L. Mc Carthy

(Division Sign-Off)

Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K052777

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