



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 17 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Keith R. Degenhardt  
Laserex Systems USA  
c/o Ellex Laser Systems  
258 Halifax Street  
Adelaide, South Australia 5000

Re: K992824  
Trade Name: Laserex Q-S/W Nd:YAG Lasers  
Regulatory Class: II  
Product Code: GEX  
Dated: August 9, 1999  
Received: August 23, 1999

Dear Mr. Degenhardt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

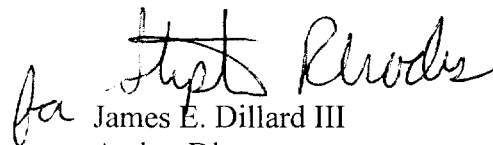
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

The signature is a cursive, handwritten name that appears to read "James E. Dillard III". To the left of the signature, the letters "fa" are handwritten.

James E. Dillard III  
Acting Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K992824

Ophthalmic Laser Models: Laserex LQ2106, Laserex LQP3106,  
Device Name: Laserex 3000LX, Alcon 3000LE, Laserex LQP4106 and Coherent "AURA"  
(Laserex LQ5106)

Indications for Use:

The indications for use for the above product family is:

- \* Iridectomy/Iridotomy.
- \* Posterior Capsulotomy.
- \* Posterior Membranectomies.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K992824

Prescription Use X  
(Per 21 CFR 801.109)

Over-the-Counter Use \_\_\_\_\_