MAY 17 [illegible]

K990665

510(k) Summary

Regulatory Authority:

Safe Medical Devices Act of 1990, 21 CFR 807.92

Company Name/Contact:

Daniel Hoefer
A.R.C. Laser Corporation
1832 South 3850 West
TEL (801) 972 1311, FAX (801) 972 5251

Name of Device

Trade Name: BQ/BM Integrated Laser Delivery System

Common Name: Laser Slit Lamp adaptor

Classification Name: Laser Adaptor for Biomicroscope, slit lamp, AC powered.

Product Code: 86 HJQ

Predicate Devices:

The BQ/BM Integrated Laser Delivery System is substantially equivalent to the following legally marketed devices: The RO 5000 AR/FDY (K973220) manufactured by G. Rodenstock Instrumente GmbH and the Zeiss 130 SL Laser Slit Lamp manufactured by Carl Zeiss.

Device Description:

When connected by fiber optic to a laser and properly attached to a 900 BQ or 900 BM slit lamp, the device directs and focuses laser energy on target tissue parfocally with the slit lamp image. An operator protective filter is incorporated into te device. The spot diameter is user adjustable, and the filter is removable to permit unimpaired viewing through the slit lamp microscope.

Intended Use:

The device is intended as a laser delivery system for use by an opthalmologist in the treatment of ocular tissue.

Technological Characteristics/Device Comparison:

The BQ/BM Integrated Laser Delivery System is intended for attachment to slit lamps that are designed for use as diagnostic instruments, enabling them to be used in the delivery of therapeutic laser energy. Like the predicate devices, laser energy is transmitted through adjustable focusing optics, which allow the user to change the diameter of the laser spot from 50 to 1000 microns. As with the predicate devices, the laser energy is directed coaxially with the slit lamp illumination and focused on the same plane. Each of the devices features operator protective filters that prevent laser treatment radiation from reaching the eyes of the user. In each case, the position of the laser spot within the focal plane is moveable using a micromanipulater.

The technological characteristics, intended use, materials, design, method of manufacture, and labeling of the device is substantially equivalent to those of the predicate devices.

Conclusion:

The BQ/BM Laser Delivery System does not raise new questions of safety and effectiveness and is substantially equivalent to the Rodenstock Ro 5000 AR/FDY and the Zeiss 130 SL.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 1999

Mr. Daniel Hoefer
Regulatory Affairs
American Laser Corporation
2417 South 3850 West
Salt Lake City, Utah 84120

Re: K990665
Trade Name: BQ/BM Integrated Laser Delivery System
Regulatory Class: II
Product Code: HQF
Dated: March 1, 1999
Received: March 2, 1999

Dear Mr. Hoefer:

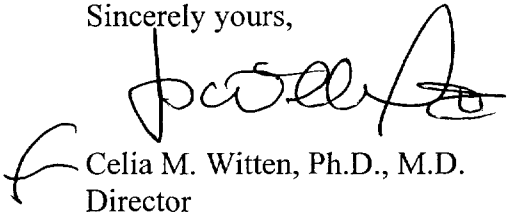
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990665

Device Name: BQ/BM INTEGRATED LASER DELIVERY SYSTEM

Indications For Use:

1. RETINAL PHOTOCOAGULATION
2. TRABECULOPLASTY

(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 General Restorative Devices
510(k) Number K990665

Prescription Use ✓ OR Over The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)