K091639

510(k) SUMMARY – Fox Q-980 Laser

Applicant Name:	A.R.C. Laser GmbH Bessemerstr. 14, D-90411 Nurnberg, Germany
Contact Person:	Angela Thyzel, General Manager
Date Prepared:	July 30, 2009
Device Trade Name:	Fox Q-980 Laser
Device Common Name: Classification Name:	Diode Laser Laser Surgical Instrument
Predicate Devices:	Fox Q-980 (K073322), LaserPro980 (K082721),
Device Description:	Fox Q-980 is a standard diode medical laser with 980nm wavelength and quartz fibers
Intended Use:	Indicated for surgical applications requiring the ablation, vaporization, excision, incision, hemostasis, or coagulation of soft tissues in medical specialties including dermatology, dentistry, gastroenterology, general surgery, genitourinary, gynecology, neurosurgery, otolaryngology, orthopedics, ophthalmology, pulmonology, thoracic surgery and laser assisted lipolysis.
Device Technological Characteristics and Comparison to Predicate Device(s):	The Fox Q-980 uses diodes to generate energy in the 980 nm range. It is the same 980 laser cleared under K073322 with the added indication for liplolysis. Another commercially available diode laser also indicated for laser assisted lipolysis is the LaserPro 980, cleared under K082721. Fibers deliver energy to the tissue for both laser models.
Performance Standards:	The Fox Q-980 Laser complies with the performance requirements of 21CFR 1040.10 and 1040.11, with permissible deviations defined in Laser Notice 50, dated July 26, 2001. The diode lasers also comply with IEC 60601-1:1998 including amendment 1, IEC 60601-2-22:1995, and IEC 60825-1:1993 including amendments 1 and 2. Sterilization of the fibers is in compliance with ISO 11135-1 and 2.
Conclusion:	The Fox Q- 980 Laser is substantially equivalent to the predicate devices. It is the same 980 nm laser cleared under K073322 and is also indicated for laser assisted lipolysis as is the LaserPro device.

AUG 13 2009

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

A.R.C. Laser GmbH
% PPD Medical Device
Ms. Kirsten H. Paulson
Manager, Regulatory Affairs
3202 Tower Oaks Boulevard, Suite 300
Rockville, Maryland 20852

AUG 18 2009

Re: K091059
Trade/Device Name: Fox Q-980 nm Diode 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 Code: GEX
Dated: August 4, 2009
Received: August 5, 2009

Dear Ms. Paulson:

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 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

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

Enclosure

Indications for Use

510(k) Number (if known): K091059

Device Name: Fox Q-980 nm Diode Laser

Indications for Use:

The Fox Q-980 Diode Laser is indicated for surgical applications requiring the ablation, vaporization, excision, incision, hemostasis, or coagulation of soft tissues in medical specialties including dermatology, dentistry, gastroenterology, general surgery, genitourinary, gynecology, neurosurgery, otolaryngology, orthopedics, ophthalmology, pulmonology, thoracic surgery and laser assisted lipolysis.

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)

(Division Sign-Off) for mxa
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091059