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510(k) SUMMARY

This 510(k) summary of safety and effectiveness for the modification in the Indications for Use for the Quantel Optimis II Q-Switched Nd:YAG Photodisruptor is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

MAR 2 4 2005

Applicant: Quantel Medical

Address: QUANTEL MEDICAL
89, Boulevard Etienne
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63100 Clermont-Ferrand
FRANCE

Contact Person: Mr. Jean Abascal
Regulatory Affairs Manager

(+33) 169 29 17 25
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Preparation Date: December 2004
(of the Summary)

Device Name: Quantel Optimis II Q-Switched Nd:YAG Photodisruptor

Common Name: Ophthalmic Laser Photodisruptor
Laser Surgical Instrument

Classification: Ophthalmic laser (21 CFR 886.4390)

Product Code: HQF; Panel: 86

Predicate devices: AURA™ (Coherent), LQP4106 ERA (Laserex), 3000 LE (Alcon), LQ2106 (Laserex), LQP3106 (Laserex) and 3000LX (Laserex) - see K992824.

Device description: The Quantel Optimis II Q-Switched Nd:YAG Photodisruptor in a Nd:YAG laser which operates at a nano-second pulse rate. The laser energy is delivered to the treatment site using a provided Optimis II slit lamp.

Indications: The Quantel Optimis II Q-Switched Nd:YAG Photodisruptor is indicated for posterior capsulotomy.

Performance Data: None required - comparison of indications and specifications/characteristics established the substantial equivalence of the Optimis II laser to predicates.

CONCLUSION: Based on the information in this notification Quantel Medical concludes that the Optimis II Q-Switched Nd:YAG Photodisruptor is substantially equivalent to the cited legally marketed predicates (K992824).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2005

Quantel Medical
c/o Mr. Roger Barnes
Regulatory Consultant
342 Sunset Bay Road
Hot Springs, Arkansas 71913

Re: K043613
Trade/Device Name: Quantel Optimis II Q-Switched Nd:YAG Photodisruptor
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: II
Product Code: HQF
Dated: December 30, 2004
Received: December 30, 2004

Dear Mr. Barnes:

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 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,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K043613

Device Name: Quantel Optimis II Q-Switched Nd:YAG Photodisruptor

Indications for Use Statement:

The Optimis II Q-Switched Nd:YAG Photodisruptor is intended for posterior capsulotomy.

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

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X OR Over-The Counter Use ___
(Per 21 CFR 801.109)

Restorative
Devices
K043613