DEC 17 2002

SECTION 10

K023094

510(k) SUMMARY

This 510(k) summary of safety and effectiveness for the modification in the Indications for Use for the Iridis Ophthalmic Photocoagulator 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.

Applicant: Quantel Medical

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Contact Person: Mr. Jean Abascal

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Preparation Date: September 2002
(of the Summary)

Device Name: Iridis Ophthalmic Photocoagulator

Common Name: Ophthalmic Laser, 810 nm diode laser
Laser Surgical Instrument; 810 nm diode laser

Classification Name: Ophthalmic laser (see 21 CFR 886.4390)
Laser surgical instrument (see: 21 CFR 878.4810).

Product Code: HQF; Panel: 86
Product Code: GEX; Panel: 79

Predicate devices: Iris Medical OcuLight SL/SLx (K020374); Nidek DC-3300 (K013760)

The predicate lasers utilize several delivery systems, including slit lamp adapters, biomicroscopes, endoprobes, and indirect ophthalmoscopes to deliver the laser energy to the treatment site.

The delivery systems used with the Iridis Ophthalmic Photocoagulator are the same as or similar to delivery systems supplied with or used with other ophthalmic photocoagulators operating at 810 nm. Quantel Medical has identified model or product numbers of the delivery systems which may be used with the Iridis Ophthalmic Photocoagulator. These devices are independently marketed by their respective manufacturers and are compatible for use with the Iridis Ophthalmic Photocoagulator.

Device description: The Iridis Ophthalmic Photocoagulator consists of a main console with controls and a foot switch. The laser emits a coherent beam of light at 810 nm. Delivery systems attached to the laser then transmit the beam to treatment sites within the eye. The delivery systems are independent devices, manufactured by independent manufacturers, which attach to the Iridis Ophthalmic Photocoagulator either by direct connection at the laser aperture or through attachments, such as the slit lamp adapter.

Indications: The Quantel Iridis Ophthalmic Photocoagulator is indicated for the photocoagulation or ablation of pigmented tissue within the eye.

Examples include:

photocoagulation of pigmented tissue within the eye,
transscleral ciliary body ablation (treatment is reserved for patients with chronic glaucoma and those not responding to conventional treatments),
limited and pan-retinal photocoagulation,
transpupillary photocoagulation,
endophotocoagulation,
treatment of complicated rhegmatogeous, tractional retinal detachments, proliferative vitreoretinopathy, proliferative diabetic retinopathy, macular degeneration, peripheral photocoagulation (recumbent patients),
transpupillary photocoagulation of choriodal neovasculature, and
age-related macular degeneration (AMD) treatments.

Performance Data: None required.

CONCLUSION: Based on the information in this notification Quantel Medical concludes that the Iridis Ophthalmic Photocoagulator is substantially equivalent to the cited legally marketed predicates. Information regarding delivery systems which may be used with the laser is supplied by Quantel Medical; the individual devices or systems are marketed by their respective manufacturers who are responsible for complying with applicable regulations and requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2002

Quantel Medical
Roger W. Barnes
342 Sunset Bay Road
Hot Springs, Arkansas 71913

Re: K023094
Trade/Device Name: IRIDIS Ophthalmic Photocoagulator
Regulation Number: 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: HQF
Dated: September 13, 2002
Received: September 18, 2002

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.

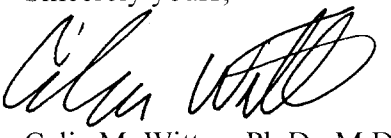
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

SECTION 7

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K023094

Device Name: Quantel Iridis Ophthalmic Photocoagulator

Indications for Use Statement:

The Quantel Iridis Ophthalmic Photocoagulator is indicated for the photocoagulation or ablation of pigmented tissue within the eye.

Examples include:

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transpupillary photocoagulation,
endophotocoagulation,
treatment of complicated rhegmatogeous, tractional retinal detachments, proliferative vitreoretinopathy, proliferative diabetic retinopathy, macular degeneration, peripheral photocoagulation (recumbent patients),
transpupillary photocoagulation of choriodal neovasculature, and
age-related macular degeneration (AMD) treatments.

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K023094

rev. 12/16/2002

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

Concurrence of CDRH, Office of Device Evaluation

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