Quantel Medical
Special 510(k)
Supra Ophthalmic Laser

APR 24 2007

510(k) Summary

K070776

(1) Submitter Information

Name: Quantel Medical

Address:

21 rue Newton - Zone du BREZET
Clermont-Ferrand 63039
France

Telephone Number: 33-1-69-29-17-00

Contact Person:
Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604
Telephone 201-727-1703
Fax 201-727-1708

Date Prepared: February 20, 2007

(2) Name of Device

Trade Name: Supra
Common Name: Ophthalmic Laser
Classification name: Laser, ophthalmic
Product Code: HQF
Regulation: 886.4390
Classification: Class II.

(3) Equivalent legally-marketed devices.

1. Quantel VITRA, K043236

(4) Description

The Quantel Supra is a modification of the Quantel Vitra, (K043236). The SUPRA laser is intended for use in photocoagulating ocular tissues in the treatment of diseases of the eye. The laser energy is delivered via either transpupillary delivery or intraocular endoprobe delivery. Both lasers are Nd: YAG laser using a KTP crystal at a wavelength of 532 nm. Its basic improvement is the increase of laser power. Controls, indications, and methods of use are basically the same. The two lasers have the same screens and functions, and differ only in that the Supra has two output ports and more output power.

(5) Intended Use

The Supra Ophthalmic Laser Photocoagulator is intended to be used for retinal photocoagulation in the following conditions:

With an indirect ophthalmoscope – for peripheral photocoagulation for the treatment of proliferative diabetic retinopathy and retinal detachments.

With an endocular probe – for intraocular retinal photocoagulation as an adjunct to vitrectomy surgery (and not for the sole indication for vitrectomy) in the management of complicated rhegmatogenous and tractional retinal detachments, proliferative vitroretinopathy, proliferative diabetic retinopathy.

With a slit lamp – for the treatment of proliferative diabetic retinopathy, choroidal neovascularization secondary to age-related macular degeneration, and retinal detachments.

(6) Performance Data

(a) Non-clinical tests

Supra has been extensively validated, both the laser itself and the software.

(b) Clinical tests

Clinical tests are not necessary, since Supra uses the same technology as the predicate device.

(c) Conclusions

Supra is equivalent in safety and efficacy to the legally-marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Quantel Medical
c/o Dr. George Myers
Medsys Inc.
377 Route 17 S.
Hasbrouck Heights, NJ 07604

APR 2 4 2007

Re: K070776
Trade/Device Name: Supra Ophthalmic Laser
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Codes: HQF
Dated: March 19, 2007
Received: March 27, 2007

Dear Dr. Myers:

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.

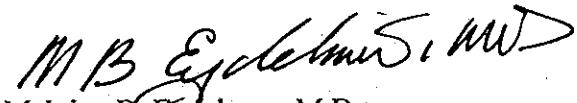
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Supra Ophthalmic Laser

Indications For Use:

The Supra Ophthalmic Laser Photocoagulator is indicated for retinal photocoagulation in the following conditions:

With an indirect ophthalmoscope - for peripheral photocoagulation for the treatment of proliferative diabetic retinopathy and retinal detachments.

With an endocular probe - for intraocular retinal photocoagulation as an adjunct to vitrectomy surgery (and not the sole indication for vitrectomy) in the management of complicated rhegmatogenous and tractional retinal detachments, proliferative vitreoretinopathy, proliferative diabetic retinopathy.

With a slit Lamp - for the treatment of proliferative diabetic retinopathy, choroidal neovascularization secondary to age-related macular degeneration, and retinal detachments.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

4/20/2007

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K070276