

MAR 25 2009

Quantel Medical
Special 510(k)
Supra Twin Ophthalmic Laser

510(k) Summary
K081946

(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: March 23, 2009

(2) Name of Device

Trade Name: Supra Twin
Common Name: Ophthalmic Laser
Classification name: Laser, ophthalmic

(3) Equivalent legally-marketed devices.

1. Quantel Supra (K070776)
2. Quantel Viridis Twin (K023464)

(4) Description

The Quantel Supra Twin is a modification of the Quantel Supra (K070776) and the Quantel Viridis Twin (K023464). The SUPRA Twin 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 of intraocular

endoprobe delivery. Both lasers are Nd: YAG laser using a KTP crystal at wavelengths of 532 nm. and 810 nm. Its basic improvement is the laser. Controls, indications, and methods of use are basically the same.

(5) Intended Use

The Supra Twin Ophthalmic Laser Photocoagulator wavelength 532nm 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 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.

810 nm Intended Use:

The Supra Twin Ophthalmic Laser Photocoagulator wavelength 810nm is intended to be used for :

Phocoagulation or ablation 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 rhegmatogenous, tractional retinal detachments, proliferative vitreoretinopathy, proliferative diabetic retinopathy, macular degeneration, peripheral photocoagulation (recumbent patients), transpupillary photocoagulation of choroidal neovasculture, and Age related macular degeneration (AMD) treatments.

(6) Performance Data

(a) Non-clinical tests

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

(b) Clinical tests

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

(c) Conclusions

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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 2009

Quantel Medical
c/o Mr. George Myers, Sc.D.
Medsys Inc.
377 Route 17 South
Hasbrouck Heights, NJ 07604

Re: K081946
Trade/Device Name: Supra Twin
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: HQF
Dated: February 27, 2009
Received: March 3, 2009

Dear Mr. 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 Twin Ophthalmic Laser

532 nm Indications For Use:

The Supra Twin Ophthalmic Laser Photocoagulator wavelength 532nm is indicated for retinal photocoagulation in the following conditions:

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Endophotocoagulation,
Treatment of complicated rhegmatogenous, tractional retinal detachments, proliferative vitreoretinopathy, proliferative diabetic retinopathy, macular degeneration, peripheral photocoagulation (recumbent patients), transpupillary photocoagulation of choroidal neovasculture, and Age related macular degeneration (AMD) treatments.

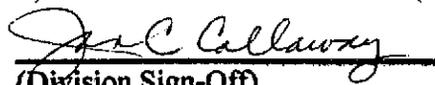
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)


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

510(k) Number K081946