510(k) SUMMARY

K091581

JUN 16 2009

I. General information

Applicant: Quantel Medical

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Contact Person:
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Preparation Date: (of the Summary) November 2008

II. Name

Device Name: SUPRA 577.Y Laser

Common Name: SUPRA 577.Y Laser

Classification Name: Ophthalmic laser (see 21CFR 886.4390)

Product Code: HQF ; Panel: 86

III. Predicate Device

IRIDEX IQ 577 Laser (K071687)

IV. Product Description

The Quantel SUPRA 577.Y Laser is a semi conductor laser which emits a beam of coherent light at 577 nm. The energy is delivered to the treatment site(s) via delivery systems/devices.

V. Indications for Use

The SUPRA 577.Y Laser is indicated for use in photocoagulation of both anterior and posterior segments including:
◆ Retinal photocoagulation, panretinal photocoagulation and intravitreal endophotocoagulation of vascular and structural abnormalities of the retina and choroids including:

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1. Proliferative and nonproliferative diabetic retinopathy;
2. choroidal neovascularization;
3. branch retinal vein occlusion;
4. age-related macular degeneration;
5. retinal tears and detachments;
6. retinopathy of prematurity;

◆ Iridotomy, iridectomy and trabeculoplasty in angle closure glaucoma and open angle glaucoma.

VI. Device Technological Characteristics and comparison to Predicate Device

SUPRA 577.Y share the same indications for use and safety compliance, similar design features, functional features, and therefore are substantially equivalent to the predicate device , the IRIDEX IQ 577 Laser (K071687). In addition a review of the predicate device demonstrate that the SUPRA 577.Y Laser is safe and effective as the predicate device as they share equivalent wavelengths, power, exposure time and are used to perform the same indicated surgical procedures.

VII. Performance Standard

SUPRA 577.Y is designed, tested and will be manufactured in accordance with both mandatory and voluntary standards, including:

- IEC 60825-1:2007, Safety of laser products – Part 1 : Equipment classification, requirements and user's guide.
- IEC 60601-2-22: 2007, Medical electrical Equipment – Part 2 : Particular requirements for the safety of diagnostic and therapeutic laser equipment.
- IEC 60601-1: 1998 + A1:1991+A2:1995, Medical Electrical equipment – Part 1 : general requirement for safety.
- IEC 60601-1-2: 2001 +A1:2004. Medical Electrical equipment – Part 1 : General requirements for safety-2, Collateral Standard : electromagnetic compatibility – requirements and tests.

The device also complies with European Medical Directive 93/42/EEC and the US Federal Performance Standards 21 CFR 1002.10 Requirements (21 CFR 1040.10 and 21CFR1040.11 for Class IV Laser Products with permissible deviations defined in Laser Notice 50, dated July 26, 2001.), Part 820 – Quality System Regulation, and have passed ISO 9001 and 13485 System Certification.

Non clinical Conclusion:
Laboratory testing was conducted to validate and verify that the proposed device, SUPRA 577.Y met all design specifications and was substantially equivalent to the predicate device.

Clinical Conclusion: No Clinical information is required.

VIII. Conclusion

Based on the information in this notification Quantel Medical concludes that the SUPRA 577.Y Laser is substantially equivalent (SE) to the cited legally marketed predicate. 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 have the responsibility for complying with applicable regulations and marketing requirements.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

Quantel Medical
c/o Tamas Borsai
Division Manager, Medical Division
TUV Rheinland of North America
12 Commerce Rd.
Newton, CT 06470

JUN 16 2009

Re: K091581
Trade/Device Name: SUPRA 577.Y LASER
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: II
Product Code: HQF
Dated: May 28, 2009
Received: June 2, 2009

Dear Mr. Borsai:

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,

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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 091581

Device Name: Supra 577.Y

Indications for Use Statement:

The Supra 577.Y Laser system and accessories that are used with it to deliver laser energy in either CW pulse, MicroPulse or Long Pulse mode in the medical specialties of ophthalmology as follows:

Ophthalmology:

Indicated for use in photocoagulation of both anterior and posterior segments including:
◆ Retinal photocoagulation, panretinal photocoagulation and intravitreal endophotocoagulation of vascular and structural abnormalities of the retina and choroids including:

1. Proliferative and nonproliferative diabetic retinopathy;
2. choroidal neovascularization;
3. branch retinal vein occlusion;
4. age-related macular degeneration;
5. retinal tears and detachments;
6. retinopathy of prematurity;

◆ Iridotomy, iridectomy and trabeculoplasty in angle closure glaucoma and open angle glaucoma.

(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)

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

510(k) Number K091581