K100678

JUL 21 2010

SECTION 17

Executive Summary
510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

I. General information

Applicant: Quantel Medical

Address: QUANTEL MEDICAL
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Contact Person: Mr. Patrick QUERO
Quality Director & Regulatory Affairs
(+33) 473 74 57 45
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Summary Preparation Date: July 2009

II. Name

Device Name: SUPRA SCAN™ Delivery System

Common Name: SUPRA SCAN™ Delivery System

Classification Name: Laser instrument, surgical, powered (see 21CFR 878.4810)

Product Code: GEX ; Panel: 79

III. Predicate Device

OptiMedica PASCAL Synthesis™ Delivery System (K081744)

IV. Product Description

SUPRA SCAN™ Delivery System is a scanning laser delivery system that enables the use of proprietary pattern scanning technology when coupling with laser platforms. This offers existing commercially available laser platform the ability to deliver a full spectrum of pattern scanning options.
The SUPRA SCAN™ Delivery System is intended for use by trained ophthalmologist for diagnosis and treatment of ocular pathology.
The Quantel Medical SUPRA SCAN™ Delivery System consists of the following system components:

1) Scanning Laser Delivery System adapter with scanner controls that may be coupled to a slit lamp type Haag Streit or similar models, and connected to a currently cleared Quantel Medical 532nm retinal photocoagulator (SUPRA 532).

2) Scanner control module with LCD/Touch screen, power supply, electronics and electrical connections.

V. Indications for Use

The SUPRA SCAN™ Delivery System when connected to a compatible laser system is indicated for use in the treatment of ocular pathology of anterior and posterior segments including, retinal photocoagulation, pan retinal photocoagulation for vascular and structural abnormalities of the retina and choroids including:

- Proliferative and nonproliferative diabetic retinopathy;
- Choroidal neovascularization;
- Branch retinal vein occlusion;
- Age-related macular degeneration;
- Retinal tears and detachments
- Macular edema
- Iridotomy, iridectomy and trabeculoplasty in angle closure glaucoma and open angle glaucoma.

VI. Device Technological Characteristics and comparison to Predicate Device

Predicate Product Comparison Table:

- **VI – 1 – GENERAL SPECIFICATIONS COMPARISON TABLE**

Manufacturer	**QUANTEL MEDICAL**	**OPTIMEDICA Corporation**
Model	SUPRA SCAN™ Delivery System	PASCAL Synthesis™ Delivery System
510 (K) Number		K081744
Intended Use	Photocoagulation of both anterior and posterior segments of the eye by generation of patterns of laser spots.	Photocoagulation of both anterior and posterior segments of the eye by generation of patterns of laser spots.
Type of Delivery System	Slit lamp adaptor with optical fiber connected to a laser	Slit lamp with laser integrated
Laser Energy source	Frequency doubled Nd : YAG	Frequency doubled Nd : YAG
Laser Energy Delivery	Single spot & Multi spot	Single spot & Multi spot
Spot placement	Centered on Guide Beam	Centered on Guide Beam
Laser energy Intensity	Selected by Physician	Selected by Physician
Pulsing System	Continuous	Continuous
Power requirements : Current	1 A	---
Computer control	Yes	Yes
Can user change computer program ?	No	No

VI – 2 – LASER ENERGY SOURCE COMPARISON TABLE

Manufacturer	**QUANTEL MEDICAL**	**OPTIMEDICA Corporation**
Model	SUPRA 532	Pascal ™Photocoagulator
510 (K) Number	K070776	K043486
Lasing Medium	Frequency doubled Nd : YAG	Frequency doubled Nd : YAG
Pulsing System	Continuous	Continuous
Output Wavelength	532 nm	532 nm
Average Power (AP)	2W with SUPRA Scan	2 W
Laser Safety Class	4/IV	4/IV
Exposure Selections (t)	0.007s to continuous	0.01s to continuous
Cooling Method	Solid State Cooling with thermoelectric (Peltier) heat pump	Air cooled
Aiming Beam :	Coaxial with treatment beam	
Aiming Beam : Type	Red diode	Red diode
Aiming Beam : Wavelength	635 nm	635 nm
Aiming laser power	< 1mW	< 1mW
Laser Safety Class	2/II	2/II
Power requirements : Voltage	100 to 240 Vac	100 to 240 Vac
Power requirements : Current		5 A
Computer control	Yes	Yes
Can user change computer program ?	No	No
Safety measures	Conform to standard 60601-2-22 and 60825-1	Conform to standard 60601-2-22 and 60825-1

- VI – 3 – LASER CHARACTERISTICS COMPARISON TABLE

Manufacturer	**QUANTEL MEDICAL**	**OPTIMEDICA Corporation**
Model	SUPRA SCAN™ Delivery System connected to SUPRA 532	PASCAL Synthesis™ Delivery System
510 (K) Number		K081744
User interface	Touchscreen	Touchscreen
Dimensions	5,8in H x 13in W x 12,1in D	---
Power calibration	YES	YES
Laser Energy Delivery	**Multi-Spot Mode**	**Multi-Spot Mode**
Mini focal spot size diameter	100µm	100µm
Exposure Selections (Multi spot mode)	0.01s to continuous	0.01s to continuous
Mini focal spot size : (area)	7.8539×10^{-5} cm²	7.8539×10^{-5} cm²
Average Power Density (APD=AP/area)	0.2546×10^{5} W/cm²	0.2546×10^{5} W/cm²
Energy max at minimum exposure (APx t)	20mJ	20mJ
Max energy density at min exposure (APxt/area)	0.254×10^{3} J/cm²	0.254×10^{3} J/cm²
Mini focal spot size diameter	500 µm	400 µm
Mini focal spot size : (area)	$1,9635 \times 10^{-3}$cm²	$1,256\ 10^{-3}$cm²
Average Power Density (APD=AP/area)	$1,02 \times 10^{3}$ W/cm²	$1,59 \times 10^{3}$ W/cm²
Energy max at minimum exposure (APx t)	20mJ	20mJ
Max energy density at min exposure (APxt/area)	102 mJ/cm²	159 mJ/cm²
Laser Energy Delivery	**Single spot Mode**	**Single spot Mode**
Mini focal spot size diameter	**50µm**	**60 µm**
Exposure Selections (Single spot mode)	0.007s to continuous	0.01s to continuous
Mini focal spot size : (area)	**$1,9635 \times 10^{-5}$ cm²**	**$2,8274 \times 10^{-5}$ cm²**
Average Power Density (APD=AP/area)	**$1,02 \times 10^{5}$ W/cm²**	**$0,7073 \times 10^{5}$ W/cm²**
Energy max at minimum exposure (APx t)	**14mJ**	**20mJ**
Max energy density at min exposure(APxt/area)	**71 mJ/cm²**	**71 mJ/cm²**

- VI – 4 – SYSTEM CHARACTERISTICS COMPARISON TABLE

Manufacturer	**QUANTEL MEDICAL**	**OPTIMEDICA Corporation**
Model	SUPRA SCAN™ Delivery System	PASCAL Synthesis™ Delivery System
510 (K) Number	----	K081744
User interface	Touch screen + manual zoom	Touch screen
Dimensions	Screen : 20cm H x 12cm W x 4cm D Adaptor : 25cm H x 20cm W x 13cm D	122cm H x 76cm W x 122cm D
Weight	2 kg	137 kg
Focal spot size diameters available	Continuously adjustable with parafocal zoom from 50µm to 500µ	4 sizes available : 60µm – 100µm – 200µm – 400µm
Spot size adjustment	Manually on the zoom	From touch screen
Type of patterns available	Square – Triple arc – Circle – Macular grid	Square – Triple arc – Circle – Macular grid - Octant
Repetition rate between two spots	8ms	8ms
Type of scanning system	scanners	scanners
Filter protection integrated	YES	YES

VII. Performance Standard

SUPRA SCAN™ Delivery System 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: Ed 1995, Medical electrical Equipment – Part 2 : Particular requirements for the safety of diagnostic and therapeutic laser equipment.
- IEC 60601-1: 1988 + A1:1991 + A2:1995, Medical Electrical equipment – Part 1 : general requirement for safety.
- IEC 60601-1-2: 2001, Medical Electrical equipment – Part 1 : General requirements for safety-2, Collateral Standard : electromagnetic compatibility – requirements and tests.
- IEC 60601-1-4: 2000, Medical electrical equipment - Part 1 : General requirements for safety -4 - Collateral standard : Programmable electrical medical systems, edition 1.1

The device also complies with European Medical Directive 93/42/EEC + Amendment 2007/47/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 1010.2 and 1010.3,Part 820 – Quality System Regulation, and have passed ISO 9001 and 13485 System Certification.

VIII. Discussion of similarities and Differences with the Predicate Product

SUPRA SCAN™ Delivery System share the same indications for use and safety compliance, similar design features, functional features, and therefore are substantially equivalent to the predicate device , the PASCAL Synthesis™ Delivery System (K081744). In addition a review of the predicate device demonstrate that the SUPRA SCAN™ Delivery System is safe and effective as the predicate device as they share equivalent specifications / characteristics and are used to perform the same indicated surgical procedures.

The only differences in the specifications/characteristics of the SUPRA SCAN™ Delivery System and its predicate PASCAL Synthesis™ Delivery System (K081744) is that :

1. The SUPRA SCAN™ Delivery System has a maximum spot size of 500 microns instead of 400 microns for PASCAL Synthesis™ Delivery System. This difference is not viewed as being clinically significant. SUPRA SCAN™ Delivery System offers to treat at 400 microns with equivalent energy output performance.

Conclusion:

SUPRA SCAN™ Delivery System use the same fundamental technology features as the PASCAL Synthesis™ Delivery System (K081744) and delivers the same level of effectiveness. Therefore, it is concluded that there is no significant difference in the basic function, safety and effectiveness between the PASCAL Synthesis™ Delivery System (Predicate Device) and the SUPRA SCAN™ Delivery System.

IX. Non-clinical performance data and conclusions from non-clinical tests

Laboratory testing was conducted to validate and verify that the proposed device, SUPRA SCAN™ Delivery System met all design specifications and was substantially equivalent to the predicate device.
Clinical Conclusion: No Clinical information is required.

X. Conclusion

Based on the information in this notification Quantel Medical concludes that the SUPRA SCAN™ Delivery System is substantially equivalent (SE) to the cited legally marketed predicate.

The potential hazards. e.g. are controlled by a risk management plan including :

- A hazard identification (Section 9)
- A Risk evaluation (Section 9)
- A software Development and Validation Process (Section 10).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 21 2010

Quantel Medical
% TUV Rheinland of North America, Inc.
Mr. Tamas Borsai
12 Commerce Road
Newton, Connecticut 06470

Re: K100678
Trade/Device Name: Supra Scan™ Delivery System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: July 19, 2010
Received: July 19, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

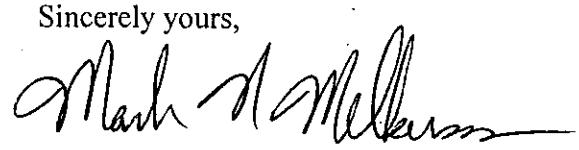
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): __K

Device Name: SUPRA SCAN™ Delivery System

Indications for Use Statement:

The SUPRA SCAN™ Delivery System when connected to a compatible laser system is indicated for use in the treatment of ocular pathology of anterior and posterior segments including, retinal photocoagulation, pan retinal photocoagulation for vascular and structural abnormalities of the retina and choroids including:

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- Choroidal neovascularization;
- Branch retinal vein occlusion;
- Age-related macular degeneration;
- Retinal tears and detachments
- Macular edema
- 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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100678