AUG 1 1 2011

Section 5 – 510(k) Summary

K111108

I. General Information

Submitter: Topcon Medical Laser Systems, Inc.
3130 Coronado Drive
Santa Clara, CA 95054, USA

Contact Person: John Jossy
Director of Quality Assurance and Regulatory Affairs
408-235-8202

Summary Preparation Date: June 7, 2011

II. Names

Device Name(s): PASCAL® Streamline 577 (with Accessories)

Primary Classification Name(s): Ophthalmic laser; Laser powered surgical device

III. Predicate Devices

- PASCAL Streamline Photocoagulator, now owned/manufactured by Topcon Medical Laser Systems (TMLS; previously owned by OptiMedica) (K100019)
- SUPRA 577.Y Photocoagulator, manufactured by Quantel Medical (K091581)
- IQ 577 Photocoagulator, manufactured by IRIDEX Corp. (K071687)

IV. Product Description

The PASCAL® Streamline 577 (with Accessories) is an Optically Pumped Semiconductor Laser (OPSL; solid state) with integrated slit lamp that is intended for use in ophthalmic applications. The PASCAL® Streamline 577 system delivers 577 nm laser light (yellow) at a spot size range of 60 – 400 micrometers (μm) to the focal plane of the slit lamp. The integrated slit lamp allows the physician (using a physician selected lens) to deliver the laser light to the treatment site. The treatment laser delivers single pulses or a scanned pattern of 100 to 2000 milliwatts (mW) per pulse with a pulse duration of approximately 5 – 1000 milliseconds (ms) per pulse. A diode laser (635 nm) provides a visible aiming beam.

Laser light is delivered to the treatment site via the integrated slit lamp or via an optional Laser Indirect Ophthalmoscope (LIO) 577 with eye safety filter for ophthalmic indications.

The physician is able to control the delivery of laser energy using a footswitch.

The PASCAL® Streamline 577 (with Accessories) is comprised of the following functional components:

- Slit Lamp Table with integrated 577 nm laser system:
  - 577 nm Laser system control electronics and power supply;
  - Control Panel with LCD (liquid crystal display) Touchscreen;
  - Keyswitch;
  - Emergency Laser Stop Button;

- Footswitch;
- Door Interlock Plug;
- Power cable [4.6 m (15 ft.) long]
- Connector Ports for the table lift power connector, the table lift up/down control connector, the door interlock connector, the footswitch connector, and a USB connector for an optional printer.
- Rolling base with lockable wheels.
- Printer (optional).

- Slit Lamp with integrated scanning pattern generator (and laser eye safety filter).

Accessories (Optional)

- Laser Indirect Ophthalmoscope (LIO) 577 with eye safety filter.
- Video Teaching System (VTS).
- Physician Elbow Rest.

V. Intended Use & Indications for Use

The PASCAL® Streamline 577 (with Accessories) is intended for use in the treatment of ocular pathology in the posterior segment; Retinal photocoagulation, panretinal photocoagulation, focal photocoagulation and grid photocoagulation for vascular and structural abnormalities of the retina and choroid including:

- proliferative and nonproliferative diabetic retinopathy
- macular edema
- choroidal neovascularization
- branch and central retinal vein occlusion
- the treatment of choroidal neovascularization associated with wet age-related macular degeneration
- lattice degeneration
- retinal tears and detachments
- retinopathy of prematurity

Intended for use in the treatment of ocular pathology in the anterior segment including:

- iridotomy
- trabeculoplasty

VI. Summary of Technological Characteristics

The technological characteristics of the PASCAL® Streamline 577 (with Accessories) are substantially equivalent to those of the predicate devices.

Characteristics	**K11** PASCAL Streamline 577 (with Accessories); Topcon Medical Laser Systems	**K100019** PASCAL Streamline Photocoagulator; OptiMedica (now Topcon Medical Laser Systems)	**K091581** SUPRA 577.Y Photocoagulator; Quantel Medical	**K071687** IQ 577 Photocoagulator; IRIDEX Corp
Treatment Laser				
Treatment λ	577 nm	532 nm	577 nm	577 nm
Laser Type	OPSL – Optically Pumped Semiconductor Laser	OPSL – Optically Pumped Semiconductor Laser	Diode Pumped; Solid State	Diode Pumped; Solid State
Power output	0 – 2000 mW	100 mW – 2000 mW	Up to 2000 mW	Up to 5000 mW
Duty cycle	100%	100%	Not reported	Variable
Pulse Duration	5 ms – 1000 ms	10 ms – 1000 ms	10 ms to continuous	10 µs – 60 min
Repetition Rate	Off, 1.0, 1.5, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0, and 8.0 Hz (available w/ single spot pattern only)	Off, 1.0, 1.5, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0, and 8.0 Hz (available w/ single spot pattern only)	Not reported	≤ 1 kHz
Pulse counter	0 – 99,999	0 – 99,999	Not reported (pulse counter present)	Not reported (pulse counter present)
Aiming Beam				
Aiming Beam λ (power output)	635 nm; Direct diode (Adjustable to <1 mW)	635 nm; Direct diode (Adjustable to <1 mW)	635 nm; diode	630 – 670 nm (diode), <1.0 mW
Other Specifications				
Spot diameter	Slit Lamp Microscope (integrated) • 60 – 400 µm delivered to the focal plane of the slit lamp in air.	Slit Lamp Microscope (integrated) • 60 – 400 µm delivered to the focal plane of the slit lamp in air.	Microscope Adapter • 50 – 500 µm	Microscope Adapters – 577 nm SLA/OMA Spot Size Ranges: 50 - 5000 µm to the retina
	LIO 577 • 360 µm (at fundus w/ 20D lens)	LIO - 532 • 360 µm (at fundus w/ 20D lens)	LIO – 577 nm Unknown spot diameter	LIO – 577 nm 360 µm & 1.3 mm (at retina w/ 20D lens)

VII. Rationale for Substantial Equivalence

The PASCAL® Streamline 577 (with Accessories) shares the same or similar indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate devices.

VIII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics demonstrates that the PASCAL® Streamline 577 (with Accessories) is substantially equivalent to the predicate devices.

IX. Conclusion

The PASCAL® Streamline 577 (with Accessories) was found to be substantially equivalent to the predicate devices.

The PASCAL® Streamline 577 (with Accessories) shares the same or similar indications for use, similar design features, and functional features with, and thus is substantially equivalent to, the predicate devices.

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

Topcon Medical Laser Systems, Inc.
% Mr. John Jossy
Director, Quality Assurance and
Regulatory Affairs
3130 Coronado Drive
Santa Clara, California 95054

AUG 1 1 2011

Re: K111108
Trade/Device Name: PASCAL Streamline 577 (with Accessories)
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: HQF
Dated: June 07, 2011
Received: June 09, 2011

Dear Mr. Jossy:

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.

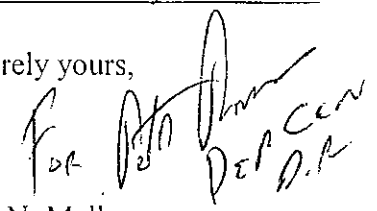
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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): **K111108**

Device Name: PASCAL® Streamline 577 (with Accessories)

Indications for Use:

PASCAL® Streamline 577 (with Accessories) is intended for use in the treatment of ocular pathology in the posterior segment; Retinal photocoagulation, panretinal photocoagulation, focal photocoagulation and grid photocoagulation for vascular and structural abnormalities of the retina and choroid including:

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Intended for use in the treatment of ocular pathology in the anterior segment including:

- iridotomy
- trabeculoplasty

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark R Ogden for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111108