MAY 1 5 2013

5IO (K) SUMMARY – K123542

I. General Information

Submitter:	Topcon Medical Laser Systems, Inc. 3130 Coronado Drive Santa Clara, *CA 95054*, USA
Contact Person:	Pamela M. Buckman Regulatory Consultant T 925 980 7007 F 925 705 7381 pmbuckman@gmail.com
Summary Preparation Date:	May 12, 2013

II. Names

Device Name(s):	PASCAL® Synthesis™ Ophthalmic Scanning Laser System
Common Name:	Laser, Ophthalmic
Classification Name(s):	Laser Surgical Instrument for use in General and Plastic Surgery and Dermatology; Laser, Powered

III. Predicate Devices

- Optimedica Ophthalmic Scanning Laser System (K092621)
- Topcon Ophthalmic Scanning Laser System (Kl 11108)
- Iridex TxCell Adaptor/Photocoagulator System (K121475)

IV. Product Description

The PASCAL® Synthesis™ Ophthalmic Scanning Laser System is a stand-alone laser delivery console for use with a slit lamp, LIO or probe delivery. Controls and displays include an LCD/Touchscreen user interface and a slit lamp connector (SLC). The system is equipped with a three-position key switch that enables laser and controls as well as an emergency off switch. An externally connected wired footswitch activator is provided with a shrouded housing, and contains a set of redundant switches. An external door interlock connection allows the laser to be terminated with an open circuit.

V. Summary of Non Clinical Tests

Topcon utilized hardware testing (60601-1, -2-x; EN ISO14971-C; ASTM 4169-09&6653-01; ASTM D4169-09), electromagnetic testing (IEC 60601-1-2, 4, 6) software testing (EN 60601-1-41 62304 and animal testing to establish a basis for the determination of equivalence. The PASCAL® Synthesis performance characteristics were established by referencing the known performance characteristics of the predicate device. Specifications for the PASCAL® Synthesis system were established to assure that the predicate system and the Synthesis system performed in an equivalent manner. Performance specifications were set utilizing national and international standards for such devices with respect to output, indications for use, safety features and electromagnetic interference where it was established as suitable for the environment of use. All testing was conducted and established that the PASCAL® Synthesis system met or exceeded its design specifications and performed equally or better than the stated performance of the predicate.

The objective of the animal study was to compare the appearance of retinal laser lesions produced by the PASCAL Synthesis system with the predicate PASCAL Streamline system in an animal model. This prospective comparative study included delivery of laser lesions to two animals in accordance with Good Laboratory Practices (GLP) standards and the local Animal Institutional Review Board. Multiple lesions using varying spot sizes and intensities were created with each of the two lasers and assigned a clinical grade by the laser operator on a 5 point scale. When comparing lesions of the same clinical grades, the appearance of the lesions was similar. The diameter of the lesions was <20% in mean diameter. Within lesions of the same clinical grade, the variability was approximately 10%. Lesions were created using spot sizes of 100, 200 and 400 micron (50 micron was not part of the investigation). Powers ranged from 70 mW to 450 mW. Endpoint Management algorithms were not used as part of this investigation. No systematic trend in lesion diameter was observed. The Streamline device and the Synthesis device were comparable in a preclinical setting.

Conclusions drawn from these non-clinical tests demonstrate that the device is as safe, as effective and performs at least as safely and as effectively as the legally marketed device identified in this Summary.

VI. Indications for Use

The PASCAL® Synthesis Ophthalmic Scanning Laser System is intended for use in the treatment of ocular pathology in both the posterior and anterior segments. Intended for use in the posterior segment to perform retinal photocoagulation, panretinal photocoagulation, focal photocoagulation and grid photocoagulation for vascular and structural abnormalities of the retina and choroid including:

(532nm)

- proliferative and non-proliferative diabetic retinopathy
- macular edema
- choroidal neovascularization associated with wet age-related macular degeneration
- age-related macular degeneration
- lattice degeneration
- retinal tears and detachments

(577nm)

- proliferative and non-proliferative diabetic retinopathy
- macular edema
- choroidal neovascularization associated with wet age-related macular degeneration
- age-related macular degeneration
- lattice degeneration
- retinal tears and detachments

Intended for use in the treatment of ocular pathology in the anterior segment including: (532 nm and 577nm)

- iridotomy
- trabeculoplasty.

VII. Summary of Technological Characteristics

The technological characteristics of the PASCAL® Synthesis Ophthalmic Scanning Laser System are substantially equivalent to those of the predicate.

Technical Characteristics	K092621	K111108	K121475/K071687	K123542 PASCAL® Synthesis
Type of Laser	OPSL – Optically Pumped Semiconductor Laser; Diode Pumped; Solid State	OPSL – Optically Pumped Semiconductor Laser; Diode Pumped; Solid State	OPSL – Optically Pumped Semiconductor Laser; Diode Pumped; Solid State	OPSL – Optically Pumped Semiconductor Laser; Diode Pumped; Solid State
Output Wavelength	532 nm	577 nm	532 nm or 577 nm	532 nm or 577 nm
Power output	0, 100 mW – 2000 mW	0, 100 mW – 2000 mW	0-2000 mW	0, 30 mW – 2000 mW
Duty cycle	100%	100%	Variable	100%
Exposure time	5 ms – 1000 ms	10 ms – 1000 ms	.05 ms – 3000 ms	2 ms – 1000 ms
Repetition Rate (available with single spot pattern only)	Off, 1.0hz, 1.5hz, 2.0hz, 3.0hz, 4.0hz, 5.0hz, 6.0hz, 7.0hz, 8.0hz	Off, 1.0hz, 1.5hz, 2.0hz, 3.0hz, 4.0hz, 5.0hz, 6.0hz, 7.0hz, 8.0hz	Available only with single spot pattern	Off, 1.0hz, 1.5hz, 2.0hz, 3.0hz, 4.0hz, 5.0hz, 6.0hz, 7.0hz, 8.0hz
Pulse counter	0 – 99,999 with Automatic reset	0 – 99,999, reset available	Not Reported	0 – 99,999, reset available
CDRH Classification	Class IV	Class IV	Class IV	Class IV
European MDD Classification	Class 4	Class 4	Class 4	Class 4
Type	Direct diode	Direct diode	Direct diode	Direct diode

Technical Characteristics	K092621	K111108	K121475/K071687	K123542 PASCAL® Synthesis
Wavelength	635 nm	635 nm	635 nm	635 nm
Power output	Adjustable to <1 mW	Adjustable to <1 mW	Adjustable to <1 mW	Adjustable to <1 mW
CDRH laser Classification	Class II	Class II	Class II	Class II
Electrical Requirements				
Voltage	100-240 VAC ± 10%	100-230 VAC ± 10%	100-240 VAC	100-230 VAC ± 10%
Frequency	50/60 Hz, single-phase	50/60 Hz, single-phase	50/60 Hz	50/60 Hz, single-phase
Current	<5 Amperes	<10 Amperes	Not Reported	<10 Amperes

VIII. Rationale for Substantial Equivalence

The PASCAL® Synthesis Ophthalmic Scanning Laser System shares the same indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate devices.

IX. Safety and Effectiveness Information

The review of the indications for use and technical characteristics demonstrates that the PASCAL® Synthesis Ophthalmic Scanning Laser System is substantially equivalent to the predicate devices. No new safety or effectiveness questions are applicable.

X. Conclusion

The PASCAL® Synthesis Ophthalmic Scanning Laser System was found to be substantially equivalent to the predicate devices. The PASCAL® Synthesis Ophthalmic Scanning Laser System shares the same indications for use, similar design features, and functional features with, and thus is substantially equivalent to, the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Topcon Medical Laser Systems, Inc.
% Buckman Company, Inc.
Ms. Pamela M. Buckman
Regulatory Consultant
2800 Pleasant Hill Road, Suite 175
Pleasant Hill, California 94553

May 15, 2013

Re: K123542
Trade/Device Name: PASCAL® Synthesis™ Ophthalmic Scanning Laser System
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: HQF, GEX
Dated: April 15, 2013
Received: April 22, 2013

Dear Ms. Buckman:

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,
For

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K123542

Device Name: Topcon PASCAL® Synthesis Ophthalmic Scanning Laser System

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

(532 nm and 577nm)

- iridotomy
- trabeculoplasty

X		
Prescription Use (Per 21CFR 801Subpart D)	OR	Over-The-Counter Use (21 CFR 801 Subpart C)

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

Neil R Ogden -S
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(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number K123542