K123056

510(K) SUMMARY

NOV 1 3 2012

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:	October 22, 2012

II. Names

Device Name(s):	PASCAL® Laser Indirect Ophthalmoscope
Classification Name(s):	Laser Surgical Instrument for use in General and Plastic Surgery and Dermatology

III. Predicate Devices

- Optimedica Laser Indirect Ophthalmoscope (K062336)
- Topcon Laser Indirect Ophthalmoscope (K111108)

IV. Product Description

The PASCAL Laser Indirect Ophthalmoscope (LIO) with eye safety filter is a non-sterile, multiple use, delivery device that is worn on the physician's head and is used in conjunction with a compatible hand held ophthalmoscopic examination lens to view and treat the patient's retina. LIOs are used to treat patients in a supine position or who could not otherwise be treated using a slit lamp delivery system.

V. Intended Use & Indications for Use

The PASCAL® Laser Indirect Ophthalmoscope is intended for use with the PASCAL Streamline 577 laser or the PASCAL Streamline 532 laser when either of those lasers is used 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:

532nm

- macular edema
- age-related macular degeneration
- lattice degeneration
- retinal tears and detachments

577nm

- proliferative and nonproliferative diabetic retinopathy
- macular edema
- choroidal neovascularization
- branch and central retinal vein occlusion
- 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:

577nm

- iridotomy
- trabeculoplasty

VI. Summary of Technological Characteristics

The technological characteristics of the PASCAL® Laser Indirect Ophthalmoscope are substantially equivalent to those of the predicate devices.

Characteristics	The PASCAL® Laser Indirect Ophthalmoscope Topcon Medical Laser Systems	**K062336** Topcon LIO (formerly Optimedica; now Topcon Medical Laser Systems	**K111108** LIO Accessory to Topcon PASCAL Streamline Laser System
Treatment Length	577 ±2 nm or 532 ±2 nm	532 ±2 nm	577 ±2 nm
Aiming Wavelength	635 ±10 nm	635 ±10 nm	635 ±10 nm
Eye Filter OD	> 5 @ 532 mm or > 5 @ 577 nm	> 5 @ 532 nm	> 5 @ 577 nm
Working Distance	280 mm	280 mm	280 mm
Fiber Length	5 meters	5 meters	5 meters
Aerial Spot Size	1060 µm	1060 µm	1060 µm
Illumination Source	LED and DC Battery	Halogen Cabled to DC Base Station	Halogen Cabled to DC Base Station
Cooling System	Convection Cooled Air	Convection Cooled Air	Convection Cooled Air
Weight	< 7 lbs.	< 7 lbs.	< 7 lbs.

VII. Rationale for Substantial Equivalence

The PASCAL® Laser Indirect Ophthalmoscope shares the same 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® Laser Indirect Ophthalmoscope is substantially equivalent to the predicate devices.

IX. Conclusion

The PASCAL® Laser Indirect Ophthalmoscope was found to be substantially equivalent to the predicate devices. The PASCAL® Laser Indirect Ophthalmoscope shares the same 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 Center – WO66-G609
Silver Spring, MD 20993-002

November 13, 2012

Topcon Medical Laser System, Inc. (TMLS)
% Buckman Company, Inc.
Ms. Pamela M. Buckman
2800 Pleasant Hill Road, Suite 175
Pleasant Hill, California 94523

Re: K123056
Trade/Device Name: PASCAL® Laser Indirect Ophthalmoscope
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: HQF
Dated: October 22, 2012
Received: October 24, 2012

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,

Peter D. Rumm -S

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

Enclosure

Intended/Indications for Use

510(k) Number: K123056

Device Name: Topcon PASCAL® Laser Indirect Ophthalmoscope

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577nm

- iridotomy
- trabeculoplasty

X		
Prescription Use (Per 21 CFR 801 Subpart D)	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

Neil R. Ogden for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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