November 27, 2017

Topcon Medical Laser Systems, Inc.
Sweta Srivastava
Manager, Regulatory and Clinical Affairs
606 Enterprise Ct.
Livermore, CA 94550

Re: K171488
Trade/Device Name: PSLT for PASCAL Streamline
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF, GEX
Dated: October 11, 2017
Received: October 16, 2017

Dear Sweta Srivastava:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Denise L. Hampton -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171488

Device Name
PSLT for PASCAL Streamline

Indications for Use *(Describe)*
Pattern Scanning Laser Trabeculoplasty (PSLT) software is intended for use with the PASCAL Streamline for procedures in trabeculoplasty in open angle glaucoma.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

PSLT for PASCAL Streamline

1. Submission Sponsor

Topcon Medical Laser Systems, Inc.

606 Enterprise Ct.,

Livermore,

CA, 94550

USA

Contact: Sweta Srivastava

Title: Manager, Regulatory and Clinical Affairs

Phone: 925.245.7721

2. Date Prepared

November 27, 2017

3. Device Identification

Trade/Proprietary Name:	PSLT for PASCAL Streamline
Common/Usual Name:	Laser surgical instrument
Classification Name:	Ophthalmic laser/ Powered laser surgical instrument
Regulation Number:	886.4390
Product Code:	HQF, Ophthalmic laser
Device Class:	Class II
Classification Panel:	Ophthalmic and General & Plastic Surgery

4. Legally Marketed Predicate Device(s)

Predicate Device: K100019, PASCAL® Streamline
Classification Name: Ophthalmic laser

Regulation Number: 886.4390
Product Code: HQF
Classification: Class II

Predicate Device: K111108, PASCAL Streamline 577 (with accessories)
Classification Name: Ophthalmic laser
Regulation Number: 886.4390
Product Code: HQF
Classification: Class II

Reference Device #1: K081704, Selecta Family of Laser Systems
Classification Name: Powered Laser Surgical Instrument
Regulation Number: 886.4810
Product Code: GEX, HQF
Classification: Class II

Reference Device #2: K071687, IRIDEX IQ Laser Systems
Classification Name: Powered Laser Surgical Instrument
Regulation Number: 886.4810
Product Code: GEX
Classification: Class II

5. Indication for Use Statement

Pattern Scanning Laser Trabeculoplasty (PSLT) software is intended for use with the PASCAL Streamline for procedures in trabeculoplasty in open angle glaucoma.

6. Device Description

Pattern Scanning Laser Trabeculoplasty (PSLT) is a software option for the currently marketed PASCAL Streamline (K100019 and K111108). It represents an enhancement intended to simplify the laser trabeculoplasty procedure by applying a fixed pattern of locations to the trabecular meshwork instead of a single spot. Additionally, this modification offers greater multi-functionality for the management of glaucoma. PSLT provides rapid, defined, uniform and minimally traumatic (sub-visible) computer-guided treatment with exact abutment of the patterns. The patterns readily align to the trabecular meshwork, allowing more rapid and easier applications. Once the software is enabled, the PSLT feature is always available.

7. Substantial Equivalence Discussion

The PASCAL Streamline with PSLT option has similar performance characteristics, the same environment of use and patient populations as currently marketed predicate devices. The labeling and instructional information, including warning and caution statements, is similar to that of the predicate devices. The

addition of this new feature does not raise new questions of safety and effectiveness for the PASCAL Streamline.

Table A – Comparison of Characteristics

Manufacturer	**TopCon Medical Laser Systems, Inc.**	**TopCon Medical Laser Systems, Inc.**	**Device Comparison**
Trade Name	**PASCAL Streamline PSLT**	**PASCAL Streamline**	
510(k) Number	K171488	K100019	--
Product Code	HQF	HQF	--
Regulation Number	886.4390	886.4390	--
Regulation Name	Ophthalmic laser	Ophthalmic laser	--
Indications for Use	Intended for use with PASCAL Streamline for procedures in trabeculoplasty in open angle glaucoma.	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	Different; the subject device has different indications for use, same intended use. The expanded indications for use was tested in a clinical study.

Manufacturer	TopCon Medical Laser Systems, Inc.	TopCon Medical Laser Systems, Inc.	Device Comparison
Trade Name	**PASCAL Streamline PSLT**	**PASCAL Streamline**	
		neovascularization • Branch and central retinal vein occulusion • Age-related macular degeneration • Lattice degeneration • Retinal tears and detachments Intended for use in the treatment of ocular pathology in the anterior segment including: • Iridotomy • trabeculoplasty	
Output Wavelength (nm)	532 (green)	532 (green)	Same
Treatment Laser Sources	Frequency doubled solid-state	Frequency doubled solid-state	Same
Treatment Laser Power	Up to 2W	Up to 2W	Same
Aiming Beam λ (power output)	635 nm; Direct diode (adjustable to < 1mW)	635 nm; Direct diode (adjustable to < 1mW)	Same
Type of delivery system	Slit lamp adapter with optical fiber connected to a separate laser source	Slit lamp adapter with optical fiber connected to a separate laser source	Same
Endpoint	Non-visible	Non-visible	Same
Spot size (μm)	100	50 – 400	Similar; The proposed device is different in Spot Size from the predicate, the proposed devices' pulse duration range is

Manufacturer	TopCon Medical Laser Systems, Inc.	TopCon Medical Laser Systems, Inc.	Device Comparison
Trade Name	**PASCAL Streamline PSLT**	**PASCAL Streamline**	
			cover the predicates' and both proposed device and predicate has same Fluence, therefore, this difference will not affect the substantial equivalence.
Pulse Duration	5 ms – 10 ms	10 ms – 1000 ms	Similar; less pulse duration, both have same Fluence, therefore, this difference will not affect the substantial equivalence.
Number of spots per pattern	39 spots (3 rows of 13 spots)	Single spot	Different; total number of spots more than predicate device, both have same Fluence, therefore, this difference will not affect the substantial equivalence.
Total energy delivered	3.5J	3.5J	Same
Energy per pulse	3.3 mJ	3.3 mJ	Same
Fluence	42 J/cm^2	42 j/cm^2	Same
% of TM covered	63	63	Same

Table B – Comparison of Characteristics

Manufacturer	TopCon Medical Laser Systems, Inc.	TopCon Medical Laser Systems, Inc.	Device Comparison
Trade Name	**PASCAL Streamline PSLT**	**PASCAL Streamline 577**	
510(k) Number	K171488	K111108	--

Manufacturer	**TopCon Medical Laser Systems, Inc.**	**TopCon Medical Laser Systems, Inc.**	**Device Comparison**
Trade Name	**PASCAL Streamline PSLT**	**PASCAL Streamline 577**	
Product Code	HQF, GEX	HQF	--
Regulation Number	878.4810 and 886.4390	886.4390	--
Regulation Name	Powered Laser Surgical Instrument and Ophthalmic laser	Ophthalmic laser	--
Indications for Use	Intended for use with PASCAL Streamline for procedures in trabeculopasty in open angle glaucoma.	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 • Age-related macular degeneration	Different; the subject device has different indications for use, same intended use. The expanded indications for use was tested in a clinical study.

Manufacturer	**TopCon Medical Laser Systems, Inc.**	**TopCon Medical Laser Systems, Inc.**	**Device Comparison**
Trade Name	**PASCAL Streamline PSLT**	**PASCAL Streamline 577**	
		• Lattice degeneration • Retinal tears and detachments Intended for use in the treatment of ocular pathology in the anterior segment including: • Iridotomy • trabeculoplasty	
Output Wavelength (nm)	577	577 (yellow)	Same
Treatment Laser Sources	Frequency doubled solid-state	Frequency doubled solid-state	Same
Treatment Laser Power	Up to 2W	Up to 2W	Same
Aiming Beam λ (power output)	635 nm; Direct diode (adjustable to < 1mW)	635 nm; Direct diode (adjustable to < 1mW)	Same
Type of delivery system	Slit lamp adapter with optical fiber connected to a separate laser source	Slit lamp adapter with optical fiber connected to a separate laser source	Same
Endpoint	Non-visible	Non-visible	Same
Spot size (µm)	100	60 - 400	Similar; The proposed device is different in Spot Size from the predicate, the proposed devices' pulse duration range is cover the predicates' and both proposed device and predicate has same Fluence, therefore, this difference will not affect the substantial equivalence.

Manufacturer	TopCon Medical Laser Systems, Inc.	TopCon Medical Laser Systems, Inc.	Device Comparison
Trade Name	**PASCAL Streamline PSLT**	**PASCAL Streamline 577**	
Pulse Duration	5 ms – 10 ms	5 ms – 1000 ms	Similar; less pulse duration, both have same Fluence, therefore, this difference will not affect the substantial equivalence.
Number of spots per pattern	39 spots (3 rows of 13 spots)	Single spot	Different; total number of spots more than predicate device, both have same Fluence, therefore, this difference will not affect the substantial equivalence.
Total energy delivered	3.5J	3.5J	Same
Energy per pulse	3.3 mJ	3.3 mJ	Same
Fluence	42 J/cm^2	42 j/cm^2	Same
% of TM covered	63	63	Same

8. Non-Clinical Performance Data

Software verification and validation testing was performed in accordance with FDA's Guidance for the Content of Premarket Submissions for Software contained in Medical Devices (2005). The results of all verification and validation testing demonstrate that all design and system requirements for the PASCAL Streamline with PSLT option have been met.

9. Clinical Performance Data

A clinical study was conducted to evaluate safety and efficacy of the PSLT for PASCAL Streamline to for procedures in trabeculoplasty in patients with open angle glaucoma. The study was a prospective, randomized, controlled study of patients with open angle glaucoma that required bilateral laser trabeculoplasty for intraocular pressure control. The overall design of the clinical study is shown as follows:

- Clinical Endpoints - (primary endpoint) change in IOP from baseline to 1-month post-surgery as measured by tonometry and (secondary endpoint) success at 1-month post-surgery as measured by tonometry and CLS derived parameters.

- Subject Criteria – The target population includes subjects fulfilling the standard criteria of the investigational site, who have given informed consent to participate in the study.
- Subject Inclusion/Exclusion – Inclusion - diagnosis of open angle glaucoma (OAG) including pseudo-exfoliative and pigmentary glaucoma; patients requiring bilateral laser trabeculoplasty for IOP control; structural glaucomatous damage and/or documented glaucomatous VF damage (in the previous 12 months with mean defect (MD) > 2.5 dB; no or stable anti-glaucomatous drug therapy since at least 3 months. Exclusion – refractory glaucoma, patients having undergone ocular laser procedures (SLT, LPI) or intraocular surgery for the treatment of glaucoma; corneal or conjunctival abnormality precluding contact lens adaptation; or severe dry eye syndrome.
- Study Monitoring - primary endpoints were evaluated at the 1, 3, 6, and 12-month endpoint
- Data Analysis – the modified intent to treat was used in the analysis to the data. Data were analyzed statistically using a 2-tailed unpaired *t* test, chi-square test, Mann–Whitney *U* test, repeated-measures analysis of variance. Kaplan-Meier survival analysis with Mantel-Cox log-rank test was used to compare outcomes between groups. The sample size of 58 eyes was calculated to have sufficient power (at least 80% and two-sided alpha of 0.05) to detect to reject the null hypothesis of an inter-group IOP difference of 3 mmHg with a standard deviation of 3.5 mmHg at 1 month. The chief outcome measure was absolute change in IOP from baseline.

Results of the clinical investigation support the indications for use of the PSLT for PASCAL Streamline to for procedures in trabeculoplasty in patients with open angle glaucoma by achieving clinical endpoints. Both laser modalities had similar safety and efficacy profiles. Clinical study conclusion confirms that the device is safe and effective as used according to the instructions for use.

10. Conclusion

The PSLT for PASCAL Streamline has similar intended use and technological characteristics as the predicate device, and therefore, is substantially equivalent to the predicate device. Preclinical and clinical study results demonstrate the substantial equivalence as well as the safety and effectiveness of the PSLT for PASCAL Streamline laser for use in trabeculoplasty. Additionally, the new device does not raise additional questions regarding its safety and effectiveness when compared to the predicate device(s).

The PSLT for PASCAL Streamline, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device(s).