May 25, 2018

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

Re: K180402
Trade/Device Name: PSLT with PASCAL Synthesis, PSLT with PASCAL Synthesis TwinStar
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF, GEX
Dated: March 27, 2018
Received: March 29, 2018

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 yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K180402

Device Name
PSLT with PASCAL Synthesis and PASCAL Synthesis TwinStar

Indications for Use *(Describe)*

Pattern Scanning Laser Trabeculoplasty (PSLT) software is intended for use with the PASCAL Synthesis and PASCAL Synthesis TwinStar 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

PSLT with PASCAL Synthesis and PASCAL Synthesis TwinStar

K180402

1. Submission Sponsor

Topcon Medical Laser Systems, Inc.

606 Enterprise Ct.,

Livermore,

CA, 94550

USA

Contact: Sweta Srivastava

Title: Manager, Regulatory and Clinical Affairs

2. Date Prepared

May 23, 2018

3. Device Identification

Trade/Proprietary Name:	PSLT with PASCAL Synthesis and PASCAL Synthesis TwinStar
Common/Usual Name:	Laser surgical instrument
Classification Name:	Ophthalmic laser/ Powered laser surgical instrument
Regulation Number:	886.4390 and 878.4810
Product Code:	HQF, Ophthalmic laser GEX, Laser surgical instrument for use in general and plastic surgery and in dermatology.
Device Class:	Class II
Classification Panel:	Ophthalmic and General & Plastic Surgery

4. Legally Marketed Predicate Device(s)

Predicate Device: K171488, PSLT for PASCAL Streamline, Topcon Medical Laser Systems, Inc.

The predicate device has not been subject to a design-related recall.

5. Indication for Use Statement

Pattern Scanning Laser Trabeculoplasty (PSLT) software is intended for use with the PASCAL Synthesis and PASCAL Synthesis TwinStar 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 (K171488). 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 Synthesis and PASCAL Synthesis TwinStar with PSLT option has similar performance characteristics, the same environment of use and patient populations as currently marketed predicate device. As noted in the table, the PSLT software feature in the PASCAL Synthesis and PASCAL Synthesis TwinStar do not raise any different questions of safety or effectiveness as compared to the predicate device.

Table 5A – Comparison of Characteristics

Manufacturer	**TopCon Medical Laser Systems, Inc.**	**TopCon Medical Laser Systems, Inc.**	**Device Comparison**
Trade Name	**PSLT for PASCAL Streamline**	**PSLT for PASCAL Synthesis and PASCAL Synthesis TwinStar**	
510(k) Number	K171488		--
Product Code	HQF, GEX	HQF, GEX	Same
Regulation Number	878.4810 and 886.4390	878.4810 and 886.4390	Same
Regulation Name	Powered Laser Surgical Instrument and Ophthalmic laser	Powered Laser Surgical Instrument and Ophthalmic laser	same
Indications for Use	Intended for use with PASCAL Streamline for procedures in	Intended for use with PASCAL Synthesis and PASCAL Synthesis	Same

Manufacturer	**TopCon Medical Laser Systems, Inc.**	**TopCon Medical Laser Systems, Inc.**	**Device Comparison**
Trade Name	**PSLT for PASCAL Streamline**	**PSLT for PASCAL Synthesis and PASCAL Synthesis TwinStar**	
	trabeculoplasty in open angle glaucoma.	TwinStar for procedures in trabeculoplasty in open angle glaucoma.	
Output Wavelength (nm)	532 (green) 577 (yellow)	532 (green) 577 (yellow) 638 (red)	Same; PSLT software feature will not be implemented in 638 (red) wavelength.
Treatment Laser Sources	Frequency doubled solid-state	OPSL: Optically pumped semiconductor laser; Diode pumped; solid state	Same
Treatment Laser Power	Up to 2W	0, 30 mW – 2000 mW (577) 0 to 600mW (638)	Same; PSLT will not be implemented in 638 (red) wavelength.
Aiming Beam λ (power output)	635 nm; Direct diode (adjustable to < 1mW)	635 nm; Direct diode 670nm (for TwinStar) (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	100	
Pulse Duration for PSLT feature	5 ms – 10 ms	5 ms – 10 ms	
Number of spots per pattern	39 spots (3 rows of 13 spots)	39 spots (3 rows of 13 spots)	same

Manufacturer	**TopCon Medical Laser Systems, Inc.**	**TopCon Medical Laser Systems, Inc.**	**Device Comparison**
Trade Name	**PSLT for PASCAL Streamline**	**PSLT for PASCAL Synthesis and PASCAL Synthesis TwinStar**	
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

The subject device is identical to the PASCAL Synthesis and PASCAL Synthesis TwinStar cleared under K170409. Design verification tests were performed on the identical device cleared under K170409. Testing included packaging validation and performance (bench) testing. The device passed all the testing. 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 Synthesis and PASCAL Synthesis TwinStar with PSLT option have been met.

9. Clinical Performance Data

The clinical performance testing of PSLT using the PASCAL Synthesis and PASCAL Synthesis TwinStar has not been conducted. However, the results of previous clinical performance studies to evaluate safety and effectiveness of trabeculoplasty procedures in patients with open angle glaucoma (submitted to support the premarket notification of the predicate device for PSLT, K171488) is leveraged for this submission. Both subject and predicate hardware platforms are cleared for trabeculoplasty procedures. They deliver the same magnitude of energy pulse, providing for the same total energy at the same wavelengths, and the predicate device uses the same PSLT software as that proposed in the subject device. Therefore, leveraging the clinical data of the predicate is appropriate for this submission.

The K171488 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 logrank 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 with PASCAL Streamline for procedures in trabeculoplasty in patients with open angle glaucoma by achieving clinical endpoints. Therefore, the clinical study confirms that the device is safe and effective as used according to the instructions for use.

The PSLT Software feature's specifications and performance remains unchanged from PASCAL Streamline, PASCAL Synthesis and PASCAL Synthesis TwinStar. Both laser modalities had similar safety and efficacy profiles. Hence, the results of clinical study data for 'PSLT using PASCAL Streamline' support clinical performance of PSLT with PASCAL Synthesis and PASCAL Synthesis TwinStar.

Statement of Substantial Equivalence

The results of the performance testing described above demonstrate that the PSLT with PASCAL Synthesis and PASCAL Synthesis TwinStar are as safe and effective as the predicate device and supports a determination of substantial equivalence.