September 12, 2017

Topcon Medical Laser Systems, Inc.
℅ Pamela Buckman, MSN
Regulatory Consultant
2800 Pleasant Hill Rd., Suite 175
Pleasant Hill, CA 94523

Re: K170409
Trade/Device Name: PASCAL® Synthesis™ TwinStar™ Ophthalmic Scanning Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX, HQF
Dated: August 4, 2017
Received: August 7, 2017

Dear Pamela 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 contact the Division of Industry and Consumer Education (DICE) 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. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) 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,

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
Indications for Use

PASCAL® Synthesis™ TwinStar™ Ophthalmic Scanning Laser System

Indications for Use (Describe)
PASCAL Synthesis TwinStar Ophthalmic Scanning Laser System is intended for use to perform single-spot photocoagulation in the posterior segment (retina, choroid) and in the anterior segment (iris, trabecular meshwork) as well as pattern-scanning photocoagulation in the non-macular retina of the eye. Single-spot delivery may be performed using a slit lamp biomicroscope or an indirect ophthalmoscope. Pattern delivery may be performed using a slit lamp biomicroscope.

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.

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PRASTaff@fda.hhs.gov

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1. General Information

Submission
Sponsor: Topcon Medical Laser Systems, Inc.
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F 925 245 7723
Contact Person: Sweta Srivastava

Submission Correspondent:
Pamela M. Buckman, MSN
2800 Pleasant Hill Rd., Suite 175
Pleasant Hill, CA 94523
T 925 980 7007
F 925 705 7381

Date Prepared: September 1, 2017

2. Device Identification

Device Name: PASCAL® Synthesis™ TwinStar™ Ophthalmic Scanning Laser System

Classification Name: Laser Surgical Instrument for use in General and Plastic Surgery and Dermatology; Laser, Ophthalmic

Classification Regulation: 21 CFR 878.4810
Classification Regulation: 21 CFR 886.4390

Classification Panel: Ophthalmology/General and Plastic Surgery

Product Code: GEX, HQF

Device Class: Class II

3. Predicate Devices

Primary Predicate Device

PASCAL® Synthesis™ Ophthalmic Scanning Laser System (K123542)

Reference Predicate Device

NOVUS Multiwavelength Omni (K932468)
4. **Device Description**

   PASCAL® Synthesis™ TwinStar™ is an ophthalmic scanning laser system. The system can perform single shot photocoagulation as is performed conventionally. At the physician’s discretion, the system provides for a single laser spot treatment or the option of using a selectable pattern of delivering multiple laser spots simultaneously. Pattern scanning allows the physician to enhanced efficiency and reduced patient discomfort.

   The PASCAL Synthesis™ Laser System (parent product to the PASCAL Synthesis Twinstar™) included 532 nm/577 nm wavelengths and was cleared via K123542. The subject device for this submission is a line extension named PASCAL Synthesis Twinstar and will include 577 nm/638 nm laser wavelengths.

5. **Intended Use**

   PASCAL Synthesis TwinStar Ophthalmic Scanning Laser System is intended for use to perform single-spot photocoagulation in the posterior segment (retina, choroid) and in the anterior segment (iris, trabecular meshwork) as well as pattern-scanning photocoagulation in the non-macular retina of the eye. Single-spot delivery may be performed using a slit lamp biomicroscope or an indirect ophthalmoscope. Pattern delivery may be performed using a slit lamp biomicroscope.

6. **Comparison of Technological Characteristics**

   The technological characteristics of PASCAL® Synthesis™ TwinStar™ Ophthalmic Scanning Laser System are substantially equivalent to those of the Primary predicate and the Reference predicate devices.

   The Pascal Synthesis Twinstar that is the subject of k170409 is a modification of Pascal Synthesis (primary predicate) with an added option of red treatment wavelength. Pascal Synthesis Twinstar is a combination wavelength device that offers two treatment wavelengths, i.e., 577nm and 638 nm.

   Using red laser for the treatment of eye disease, the Pascal Synthesis Twinstar uses 638 nm red laser to perform single-spot photocoagulation. The Novus Multi-wavelength (reference predicate) has been cleared for the use of similar red laser wavelength (647 nm) for the treatment of eye disease.

   The following Table compares the technological characteristics of the Pascal Synthesis Twinstar to the Primary Predicate as well as the Reference Predicate.
<table>
<thead>
<tr>
<th>ITEM</th>
<th>NOVUS Multi-Wavelength (K932468) Reference Predicate</th>
<th>PASCAL® Synthesis™ (K123542) Primary Predicate</th>
<th>PASCAL Synthesis TwinStar (K170409)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Output Wavelength³</td>
<td>521 and 531 nm (Green) 647 nm (Red) 568 nm (Yellow) 521, 531 and 568 nm (Yellow–Green)</td>
<td>532 nm (Green) 577 nm (Yellow)</td>
<td>577 nm (Yellow) 638 nm (Red)</td>
</tr>
<tr>
<td>Power Output⁴</td>
<td>Green: 50 – 900 mW Red: 50 – 1000 mW Yellow: 75 – 600 mW Yellow-Green: 75 – 1500 mW</td>
<td>0, 30 mW – 2000 Mw</td>
<td>0, 30 mW – 2000 mW (577) 0 to 600mW (638)</td>
</tr>
<tr>
<td>Duty Cycle</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Exposure Time</td>
<td>10 ms – 1000 ms, and continuous</td>
<td>2ms -1000 ms</td>
<td>2ms -1000 ms</td>
</tr>
<tr>
<td>Repetition Rate</td>
<td>Available settings range from 1 Hz to 9 Hz depending on rate and exposure time settings</td>
<td>Off, 1.0 Hz, 1.5 Hz, 2.0 Hz, 3.0 Hz, 4.0 Hz, 5.0 Hz, 6.0 Hz, 7.0 Hz, 8.0 Hz</td>
<td>Off, 1.0 Hz, 1.5 Hz, 2.0 Hz, 3.0 Hz, 4.0 Hz, 5.0 Hz, 6.0 Hz, 7.0 Hz, 8.0 Hz</td>
</tr>
<tr>
<td>Pulse Counter</td>
<td>0 – 9999, reset available</td>
<td>0-99,999, reset available</td>
<td>0-99,999, reset available</td>
</tr>
<tr>
<td>CDRH Classification</td>
<td>Class IV</td>
<td>Class IV</td>
<td>Class IV</td>
</tr>
<tr>
<td>European Classification</td>
<td>Class 4</td>
<td>Class 4</td>
<td>Class 4</td>
</tr>
<tr>
<td>Aiming Laser Type</td>
<td>InGaA1P Diode (Direct Diode)</td>
<td>Direct Diode</td>
<td>Direct Diode</td>
</tr>
<tr>
<td>Wavelength</td>
<td>670 nm</td>
<td>635 nm</td>
<td>670 nm</td>
</tr>
<tr>
<td>Power Output</td>
<td>Adjustable to &lt;1mW</td>
<td>Adjustable to &lt;1mW</td>
<td>Adjustable to &lt;1mW</td>
</tr>
<tr>
<td>CDRH Classification</td>
<td>Class IIIa</td>
<td>Class II</td>
<td>Class II</td>
</tr>
<tr>
<td>MDD Classification</td>
<td>Class 3a</td>
<td>Class 2</td>
<td>Class 2</td>
</tr>
<tr>
<td>ITEM</td>
<td>NOVUS Multi-Wavelength (K932468) Reference Predicate</td>
<td>PASCAL® Synthesis™ (K123542) Primary Predicate</td>
<td>PASCAL Synthesis TwinStar (K170409)</td>
</tr>
<tr>
<td>---------------------</td>
<td>-----------------------------------------------------</td>
<td>------------------------------------------------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>Level of Concern</td>
<td>Unknown</td>
<td>Major</td>
<td>Major</td>
</tr>
<tr>
<td>Spot Diameter</td>
<td>50 µm – 500 µm delivered to the focal plane of the slit lamp in the air (with LaserLink Z Slit Lamp Adapter) There is a laser diameter magnification factor for the contact lens utilized.</td>
<td>50 µm – 400 µm delivered to the focal plane of the slit lamp in the air. There is a laser diameter magnification factor for the contact lens utilized.</td>
<td>50 µm – 400 µm (577); 60, 200um (638) delivered to the focal plane of the slit lamp in the air. There is a laser diameter magnification factor for the contact lens utilized.</td>
</tr>
<tr>
<td>Intensity Profile</td>
<td>Top Hat</td>
<td>Top Hat</td>
<td>Top Hat</td>
</tr>
<tr>
<td>Spot Spacing</td>
<td>Not applicable (non-scanning)</td>
<td>Adjustable, with a minimum center-to-center spacing of 1 spot diameter.</td>
<td>Adjustable, with a minimum center-to-center spacing of 1 spot diameter.</td>
</tr>
<tr>
<td>Scan Field</td>
<td>Not applicable (non-scanning)</td>
<td>4 mm X 4 MM (in air)</td>
<td>4 mm X 4 mm (in air)</td>
</tr>
<tr>
<td>Scan Rate</td>
<td>Not applicable (non-scanning)</td>
<td>≤ 100 Hz</td>
<td>≤ 100 Hz</td>
</tr>
</tbody>
</table>

**Electrical Requirements:**

<table>
<thead>
<tr>
<th>ITEM</th>
<th>NOVUS Multi-Wavelength (K932468) Reference Predicate</th>
<th>PASCAL® Synthesis™ (K123542) Primary Predicate</th>
<th>PASCAL Synthesis TwinStar (K170409)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voltage</td>
<td>200-240 VAC or 380 to 415 VAC</td>
<td>100-230 VAC ± 10%</td>
<td>100-230 VAC ± 10%</td>
</tr>
<tr>
<td>Frequency</td>
<td>50/60 Hz, single phase or three-phase</td>
<td>50,60 Hz, single-phase</td>
<td>50,60 Hz, single-phase</td>
</tr>
<tr>
<td>Current</td>
<td>20, 35, or 60 A</td>
<td>&lt; 10 Amperes</td>
<td>&lt; 10 Amperes</td>
</tr>
</tbody>
</table>

### 7. Substantial Equivalence

PASCAL® Synthesis™ TwinStar™ 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. Performance and animal testing confirmed that the PASCAL® Synthesis™ TwinStar™ Ophthalmic Scanning Laser System is substantially equivalent to the identified predicates.
8. Safety and Effectiveness information

The review of the indications for use and technical characteristics as well as animal study results and performance testing demonstrate that the PASCAL® Synthesis™ Twinstar™ Ophthalmic Scanning Laser System is substantially equivalent to the predicate devices. No new safety and effectiveness questions are applicable.

9. Non Clinical Testing

Performance Testing – Bench

Performance testing was conducted in order to demonstrate compliance with recognized consensus standards:


• IEC 60601-1-2:2007: Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests

• IEC 60601-1-6:2010+A1:2013 Medical electrical equipment-Part 1-6: General requirements for safety-Collateral Standard Usability


• IEC 60825-1 2nd Edition Part 1: Safety of laser products-Part 1: Equipment classification and requirements Additionally, hardware and software validation activities were performed to ensure the device performed as intended and software documentation appropriate for the Major level of concern was provided.

Performance Testing – Animal

An animal study was performed for the novel features of the subject device relative to the PASCAL® Synthesis: the 638 nm red treatment laser. In the study grids of mild to moderate grade retinal lesions were delivered to rabbit retinae in vivo with both the subject device and the reference predicate (the Novus Omni compared with the red treatment laser).
In the case of the red laser study, both 60um and 200um spot-sizes were used. Ophthalmoscopic evaluation, fundus photos, and SD-OCT measurements were taken in vivo immediately after treatment, prior to euthanasia. No difference in lesion morphology between predicate and subject device was observed funduscopically or in OCT for equivalent lesion ophthalmoscopic grade. In an analysis of OCT width measurements, the difference in lesion width for predicate and subject device was <20% in all statistically significant single-eye comparative cases. The similarity in lesion character and size under matching delivery conditions supports substantial equivalence between predicate and subject devices for the red treatment laser.

10. Clinical Performance

There was no clinical testing required to support this medical device as the indications for use and technology are equivalent to those of the predicate devices.

11. Statement of Substantial Equivalence

A device is substantially equivalent when the subject device has the same intended use and the same technological characteristics as the previously cleared predicate device(s). The addition of the red laser to the PASCAL® Synthesis™ TwinStar™ Ophthalmic Scanning Laser System does not alter either of these characteristics and does not raise any new questions of safety or efficacy as compared to the predicates.

12. Conclusion

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