October 19, 2017

Ken Nehmer
Director, Regulatory Affairs
Technolas Perfect Vision GmbH
351 Buena Vista Ave. E, Unit 501E
San Francisco, CA 94117

Re: K171014
Trade/Device Name: VICTUS Femtosecond Laser Platform
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: OOE
Dated: September 19, 2017
Received: September 20, 2017

Dear Ken Nehmer:

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,

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)*
K171014

Device Name
VICTUS Femtosecond Laser Platform

Indications for Use *(Describe)*

The VICTUS Femtosecond Laser Platform is indicated for use in:

- the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea
- for anterior capsulotomy during cataract surgery
- the creation of cuts / incisions in the cornea in patients undergoing cataract surgery or other ophthalmic treatment requiring cuts / incisions in the cornea.
- laser-assisted lens fragmentation of nuclear cataracts during cataract surgery, not for fragmentation of posterior subcapsular (PSC) and cortical cataracts

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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K171014 510(k) Summary

I. Submitter	Technolas Perfect Vision GmbH Messerschmittstr. 1 +3 80992 Munich, Germany Tel: 49 174 3494062
Contact:	Ken Nehmer Director, Regulatory Affairs Technolas Perfect Vision 351 Buena Vista Ave. E Unit 501E San Francisco, CA 94117 Ph: 415-297-0408 Email: ken.nehmer@bausch.com
Date Revised:	October 16, 2017
II. Device	
Name of Device:	VICTUS Femtosecond Laser Platform, Model 14000
Common Name:	Ophthalmic Laser
Classification Name:	Laser, Ophthalmic
Regulatory Class:	Class II
Product Code	OOE (Ophthalmic Femtosecond Laser)
Regulation Number	21 CFR 886.4390
III. Predicate Device	VICTUS Femtosecond Laser Platform (K151161) This predicate has not been subject to a design-related recall.

IV. Device Description

The VICTUS Femtosecond Laser Platform (VICTUS) is a precision ophthalmic surgical laser and is cleared for use in the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea and for patients undergoing anterior capsulotomy during cataract surgery. The VICTUS has additionally been cleared for patients undergoing cataract surgery or other ophthalmic treatment requiring penetrating arcuate cuts / incisions in the cornea, primary/secondary corneal incisions, and laser-assisted lens fragmentation.

This submission includes the next software iteration of version 3.3 and introduces a new S60 patient bed option for the VICTUS Platform. The v3.3 software introduces an additional pattern (grid pattern) which is a variation of currently cleared patterns and is being added to the already cleared lens fragmentation capability. In addition, the software introduces a lens apex detection feature.

The previously cleared patient contacting lens and previously cleared suction clip assembly are combined in one convenient package for the user as the VERAFIT patient interface kit. With the exception of the introduction of a new S60 patient bed option, the VICTUS Platform hardware remains unchanged from that described and cleared via K151161.

The mode of operation for the VICTUS Platform is using Yb:KYW Femtosecond laser to produce Laser-Induced Optical Breakdown (LIOB) of the corneal tissue. For all indications for use, laser pulses are delivered through a sterile disposable Patient Interface, consisting of a contact lens and suction clip to provide suction. The contact lens and suction clip assembly creates a reference surface for depth control and fix the eye relative to the delivery of the laser beam. Surgical effects are produced by scanning thousands of individual pulses, producing continuous incisions. The location of the tissue photodisruption is controlled by a fixed laser beam focused through a scanning optic system to the desired location.

The indications for use remains the same as previously cleared for the VICTUS Femtosecond Laser Platform under K151161.

The VICTUS Femtosecond Laser Platform main unit is composed of the following:

Component	**Description**
Assistant workstation	Allows to perform the system tests, to enter and manage the patient data, to select and program procedures, to apply vacuum for patient interface and suction clip, to adjust the procedure according to the patient's eye and to export treatment records.
Chiller	Helps to ensure that the main components are kept at a steady temperature.
Controller	Checks the connectivity among all electronic components.
GUI PC	Interface between the user and the laser

	system.
Laser source	Generates the laser beam.
Optical unit	Controls the complete laser beam path.
Surgeon control screen	Shows a live camera image, a live OCT image, and all relevant parameters for the selected treatment.
Treatment illumination	Contains the laser ring light module. It illuminates the treatment area.
Video microscope	Used as part of treatment planning and shows the top view of the eye to be treated.
OCT	Fourier based integrated optical coherence tomography unit which is used to visualize and/or position the treatment as an overlay on the video image. The OCT is not used for diagnostic purposes.
The core of the main unit is the laser source that generates the laser beam. All other components control and sustain the treatment process.	

The following components are additional features to the main unit:

Additional feature	**Description**
Surgical microscope (optional feature)	Allows for centering the suction clip
Surgical microscope illumination (optional feature)	Provides a uniform and adjustable illumination
Patient Bed	Used to position a supine patient for treatment by the VICTUS Platform.

The following components are accessories to the main unit:

Accessory	**Description**
Patient Interface Kit (PIK)	The patient interface kit is sterile, single use kit composed of a contact lens component and a suction clip component. The contact lens and suction clip assembly create a reference surface for depth control and fix the eye relative to the delivery of the laser beam.

V. Indications for Use

The VICTUS Femtosecond Laser Platform is indicated for use for:

- the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.
- for anterior capsulotomy during cataract surgery.
- the creation of cuts / incisions in the cornea in patients undergoing cataract surgery or other ophthalmic treatment requiring cuts / incisions in the cornea.

- laser-assisted lens fragmentation of nuclear cataracts during cataract surgery, not for fragmentation of posterior subcapsular (PSC) and cortical cataracts

The indications for use remain unchanged from those previously cleared via K151161.

VI. Comparison of Technological Characteristics with the Predicate

The mode of operation for the VICTUS Platform is using Yb:KYW Femtosecond laser to produce Laser-Induced Optical Breakdown (LIOB) of the corneal tissue and is the same as that previously cleared for the predicate VICTUS under K151161. Both systems deliver femtosecond pulses to produce a pattern of photodisruption to create cuts / separation in ophthalmic tissue. The subject and predicate device contain the same main unit components as described earlier in this document.

This submission includes updated software version 3.3. The version 3.3 software will only be installed on those VICTUS Platform systems that have the cleared Fourier based OCT installed. The patient interface remains the same as that previously cleared for the VICTUS Platform. The VICTUS Platform uses vacuum to affix a suction ring to the corneal surface prior to use. There is no change to vacuum suction or force pressure related to the patient interface as compared to that previously described and cleared in K151161.

The VICTUS Platform mode of operation and the technology used to create the cutting action are identical to the predicate VICTUS Platform device (K151161), and therefore substantially equivalent to the legally marketed predicate device.

The following technological differences exist between the subject and predicate devices:

a) Grid lens fragmentation pattern

The predicate VICTUS Platform includes clearance for several available lens fragmentation patterns including circular, radial, and a combination of circular and radial cuts. The v3.3 software introduces a new grid fragmentation pattern to the already available fragmentation patterns.

b) Apex detection feature

The predicate VICTUS system includes clearance for detection of pupil and lens surface. The v3.3 software introduces an apex detection feature which marks the apex location and provides an automated centration of the capsulotomy and lens fragmentation on the apex of the crystalline lens during treatment planning. The feature is being introduced as a user convenience and the physician must still review positioning results and confirm the treatment plan prior to initiating treatment.

c) S60 Bed option

A new bed configuration is being introduced that provides three locking positions as follows:

0°:	Position for treatment
16.5°:	Position for centering the patient interface (PI) or suction ring
60°:	Position for patient entrance/exit

In order to minimize manufacturing costs, it has been determined to package the predicate VICTUS contacting lens from the patient interface kit (SKU 90000115) with the suction clip from the predicate VICTUS patient interface kit (SKU 90000145) into one convenient package for the user (this new kit will be known as the VERAFIT patient interface kit –SKU 90000200TPV).

VII. Performance Data

Biocompatibility testing

No new biocompatibility testing was performed to support this premarket notification.

Electrical safety and electromagnetic compatibility (EMC)

The VICTUS Femtosecond Laser Platform has undergone testing and is in compliance with applicable safety standards as listed in the following table.

Standard	Title
EN ISO 60601-1: 2005 + A1	Medical electrical equipment – Part I: General requirements for safety
EN ISO 60601-1-2: 2007	Medical electrical equipment – Part 1: General requirements for safety; 2. Collateral standard: electromagnetic compatibility; requirements and tests
EN ISO 60601-2-22: 2007	Medical electrical equipment – Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment

The VICTUS Femtosecond Laser Platform has been found to perform equivalently to the predicate device. The VICTUS Femtosecond Laser Platform and the predicate device therefore have a similar performance profile.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern since the VICTUS Platform software controls the delivery of treatment such that an error or malfunction could result in death or serious injury.

Mechanical and acoustic testing

There was no mechanical or acoustical testing performed to support substantial equivalence of this premarket notification.

Animal Study

There was no animal study performed to support substantial equivalence of this premarket notification.

Non-Clinical Performance Data

A variety of test procedures were conducted to demonstrate that the performance of the various indications available provide substantially equivalent results when using the software version 3.3 which is subject of this premarket notification. The collected data were evaluated by comparing the mean values to the specified acceptance criteria and their 95% confidence intervals. Different materials were used for the bench performance testing including: agarose gel, polyethylene terephthalate (PETG), and polymethyl methacrylate (PMMA). The acquired test data successfully verified that the various parameters meet their pre-defined acceptance criteria.

Clinical Studies

There was no clinical study performed to support substantial equivalence of this premarket notification.

VIII. Conclusions

A majority of the technological characteristics of the VICTUS Platform are substantially equivalent to the technological characteristics of the predicate VICTUS Platform which was cleared via K151161. The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the VICTUS Platform should perform as intended in the specified use conditions.