DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 24, 2015

Technolas Perfect Vision GmbH
Mr. Ken Nehmer
Senior Manager, Regulatory Affairs
351 Buena Vista Ave. E
Unit 501 E
San Francisco, California 94117

Re: K151161
Trade/Device Name: Victus Femtosecond Laser Platform
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: OOE, HQF
Dated: April 30, 2015
Received: May 1, 2015

Dear Mr. 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 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" (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 Industry and Consumer Education 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,

Kesia Y. Alexander -A

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)*

Device Name
VICTUS Femtosecond Laser Platform

Indications for Use *(Describe)*
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

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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5. 510(k) Summary of safety and effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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Date of Summary: April 30, 2015

Trade Name: VICTUS Femtosecond Laser Platform

Common Name: Ophthalmic Laser

Classification Name: Laser, Ophthalmic

Device Classification: Class II

Product Code OOE (Ophthalmic Femtosecond Laser)
HQF (Laser, Ophthalmic)

Predicate Devices: VICTUS Femtosecond Laser Platform (K132534)

Substantially Equivalent To

510(k) Number	Product Trade Name	Manufacturer
K141379	VICTUS Femtosecond Laser Platform	Technolas Perfect Vision GmbH
K140615	VICTUS Femtosecond Laser Platform	Technolas Perfect Vision GmbH

Description of the Device Subject to Premarket Notification

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 (via K120426). The VICTUS has additionally been cleared for patients undergoing cataract surgery or other ophthalmic treatment requiring penetrating arcuate cuts / incisions in the cornea (K122386), primary/secondary corneal incisions (K132534), and laser-assisted lens fragmentation (K140615). This submission does not add to the indications previously cleared for the VICTUS Platform. With the exception of a new patient interface suction clip, the VICTUS Platform hardware and software remain unchanged from that described and cleared via K141379.

A new patient interface suction clip for the VICTUS platform is being introduced within this premarket submission, the new suction clip is smaller in diameter and contains a colorant to aid in positioning on the cornea of the eye. 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. The contact lens portion of the patient interface remains unchanged from that previously cleared. 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 fundamental scientific technology and indications for use remains the same as previously cleared for the VICTUS Femtosecond Laser Platform under K141379.

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

Technical Characteristics Comparison

The design principle of the VICTUS Platform is the same as that previously cleared for VICTUS under K141379. The VICTUS Platform mode of operation and software version (version 3.2) is the same as that previously cleared for the VICTUS Platform via

K141379 which delivers femtosecond pulses to produce a pattern of photodisruption to create cuts / separation in ophthalmic tissue.

The means of fixation (suction clip) of the patient contact portion of the VICTUS Platform has been modified as described within this premarket submission. 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 K141379.

The VICTUS Platform mode of operation and the technology used to create the cutting action are identical to the predicate VICTUS Platform device (K141379), and therefore substantially equivalent to the legally marketed predicate device.

Performance Data

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	Medical electrical equipment – Part I: General requirements for safety
EN ISO 60601-1-2	Medical electrical equipment – Part 1: General requirements for safety; 2. Collateral standard: electromagnetic compatibility; requirements and tests
EN ISO 60601-2-22	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.

Non-Clinical Performance Data

A variety of test procedures were conducted to demonstrate that the performance of the lens fragmentation indication previously cleared via K140615 (using software version 2.7 SP3) provides substantially equivalent results when using software version 3.2 (previously cleared via K141379). The collected data were evaluated by comparing the mean values to the specified acceptance criteria and their 95% confidence intervals. Four different materials were used for the bench performance testing: porcine eyes, 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 Performance Data

Clinical performance data was collected using software version 3.2 with the new OCT subassembly (data provided and cleared via K141379). An open, controlled, multi-surgeon, single-center clinical study was performed to confirm the intraoperative accuracy of biometry visualization performed by VICTUS optical coherence tomography (OCT) and its comparability with LENSTAR LS 900 by means of axial optical resolution accuracy comparison. Two groups of patients from two clinical applications i.e. femtosecond-laser flap creation (flap group – 58 eyes) and femtosecond laser assisted cataract surgery (cataract group – 113 eyes) were observed in this study. All 113 and 58 eyes assigned in the femto-cataract and flap group, respectively were available for a retrospective analysis of the correlation and agreement of the biometric data for lens thickness, anterior chamber depth (ACD) and central cornea thickness (CCT). The lens thickness, ACD and CCT measured by VICTUS OCT were compared with LENSTAR LS900 and the results are consistent.

All the enrolled cataract patients were treated with femtosecond laser assisted capsulotomy before the femtosecond laser assisted lens fragmentation by VICTUS femtosecond laser platform. The cataract group (113 eyes) represented cataract grades I through IV (Grade I = 76, Grade II = 16, Grade III = 16, Grade IV = 5). All laser assisted capsulotomy procedures were completed fully using the VICTUS laser platform with no need for manual intervention to complete the capsulotomy. There were no adverse or serious adverse events reported by the investigators during the clinical study for either the anterior capsulotomy or the lens fragmentation treatments. In addition, there were no device malfunctions which led or potentially led to adverse or serious adverse events.

Basis for Determination of Substantial Equivalence

The technological characteristics of the VICTUS Platform are substantially equivalent to the technological characteristics of the predicate VICTUS Platform which was cleared via K141379.

The indications for the VICTUS Platform remain unchanged from those cleared via K140615 and K141379.