September 1, 2020

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

Re: K200724
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: March 9, 2020
Received: March 19, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for LT Charles Chiang
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200724

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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510(K) SUMMARY

I. Submitter

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Contact

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Date Prepared September 1, 2020

II. Device

Name of Device	VICTUS Femtosecond Laser Platform
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 (K171014)
This predicate has not been subject to a design-related recall.

IV. Device Description

The VICTUS Femtosecond Laser is a precision ophthalmic surgical laser indicated for use in patients undergoing ophthalmic surgery in the anterior segment of the eye. The VICTUS Femtosecond Laser system produces scanned patterns designed to create flaps, produce corneal incisions, arcuate incisions, capsulotomy cuts, and crystalline lens fragmentation patterns for use in cataract surgery. The patient is treated while supine on a patient bed that the physician can position electromechanically via simple controls. The physician controls the

VICTUS laser system itself through a touchscreen display and other user controls. Laser emission and of PI suction vacuum are actuated by the physician using separate footswitch pedals.

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. Scanned patterns of laser pulses from the VICTUS are delivered through a sterile, disposable Patient Interface (PI). The PI consists of two components: (i) a contacting lens, and (ii) a suction clip. Together, the suction clip and contacting lens connect to make a single assembly during a VICTUS procedure. The surface of the contacting lens that contacts the eye is spherically curved to match the curvature of the human eye. The suction clip assembly gently immobilizes the eye with respect to the VICTUS laser beam and optical visualization systems. The PI contacting lens and suction clip together allow for proper optical coupling of the laser and optical paths into the patient's eye and create a precise opto-mechanical reference surface for depth control of the scanning laser beam.

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 K171014.

VI. Comparison of Technological Characteristics with the Predicate

Modifications to the VICTUS Femtosecond Laser described in this premarket notification are limited to the contacting lens component of the Patient Interface accessory and to the PI mating hardware (i.e. the Spacer Cone) that is permanently installed on the VICTUS laser. No other modifications are proposed to the cleared device.

A comparison of the technological characteristics for both the current and modified Patient Interface Kit components are provided in the following table.

TECHNOLOGICAL COMPARISON OF THE CLEARED AND PROPOSED PATIENT INTERFACE KIT COMPONENTS

	CLEARED DEVICE K171014	PROPOSED DEVICE
Trade Name – Laser System	VICTUS Femtosecond Laser Platform	Same
Indication 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	Same
Trade Name – Patient Interface Kit	VERAFIT Patient Interface Kit (SKU: 90000200TPV)	Patient Interface (PI) Kit (SKU: 90000145)
Function	Sterile, single use accessory designed to (i) provide reference surface for laser depth control and (ii) affix eye for delivery of laser beam	Same
Usage	Sterile, single use, disposable	Same
Accessory Design	Two components: contact lens suction assembly: spring clip with suction ring, tubing, vacuum reservoir w/ console connector	Same
Eye Fixation Method	Suction-fixated, curved contact	Same
Applanation Force	Shear Force: ≤ 2 N Vertical Force: Cataract indications (“soft dock”): 0.2 – 1.0 N Flaps/incisions (“hard dock”): 2.0 – 5.0 N	Same
Sterilization Method	Gamma irradiation	Same
Suction Clip Component		
Design	Limbal suction ring with spring clip	Same
Suction Method	Integrated suction ring with vacuum tubing and connector	Same

	CLEARED DEVICE K171014	PROPOSED DEVICE
Contacting Lens Component		
Manufacturing method	Machined polymeric contacting lens	Injection molded polymeric contacting lens
Contact Lens Material	PMMA	COP Zeonex
Distal (eye-contacting) radius of curvature	9.5 mm	10.5 mm
Proximal radius of curvature	17 mm	Same
Index of refraction	1.49	1.53
Maximum treatment diameter	12.0 mm	11.7 mm
Outside diameter of contacting surface	15.6 mm	same

VII. Performance Data

Biocompatibility testing

Biocompatibility assessment for the modified Patient Interface contacting lens component of the PI Kit has been performed in accordance with the requirements of ISO 10993-1 to evaluate the impact of the patient contacting material modification. Test results satisfied the acceptance criteria as defined by the associated ISO standards.

Limulus Amebocyte Lysate (LAL) testing

The VICTUS Patient Interface (PI) Kit includes a patient interface contacting lens and the suction clip ring which contact the corneal surface only (non-intraocular). Limulus Amebocyte Lysate (LAL) Endotoxin testing had been performed with results of < 1.0 EU/sample. Results are below the defined endotoxin limit for a medical device (non-intraocular) of 20 EU/medical device.

Electrical safety and electromagnetic compatibility (EMC)

No new electrical safety or EMC testing was required to support this premarket notification. The VICTUS Femtosecond Laser Platform has previously undergone testing and complies with the applicable following safety standards:

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

No new software testing was performed to support this premarket notification

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

Nonclinical performance testing was conducted to establish substantial equivalence between the Patient Interface (PI) Kit (SKU: 90000145) with the modified Patient Interface contacting lens and the PI Kit (SKU: 90000200TPV) cleared under K171014.

All bench testing results demonstrated equivalent performance between the modified and the current 510(k)-cleared PI Kits. Cuts made using the modified PI Kit were shown to be equivalent in terms of both cut pattern fidelity and cut quality to those produced with the current 510(k)-cleared PI for all cleared cataract and corneal indications for use. The docking behavior in terms of IOP safety and limbal suction integrity are equivalent between the current 510(k)-cleared and the modified (proposed) PI Kit models.

Clinical Studies

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

VIII. Conclusion

The minor modifications proposed in this 510(k) Premarket Notification did not impact the product design requirements or the conformance to applicable standards specific to this device. Any differences between the predicate and proposed devices do not affect the substantial equivalence of the device as demonstrated by the performance testing.