FEB 8 2013

K122386: 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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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)

Substantially Equivalent To:

510(k) Number	Product Trade Name	Current Manufacturer
K120426	VICTUS Femtosecond Laser Platform	Technolas Perfect Vision
K110427	Femtec Laser System for Anterior Capsulotomy	Technolas Perfect Vision GmbH
K113151	iFS Laser System	Abbott Medical Optics
K101626	LenSx Laser	LenSx, an Alcon company

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Description of the Device Subject to Premarket Notification:

The VICTUS Femtosecond Laser Platform (hereafter referred to as the VICTUS Platform) is a precision ophthalmic surgical laser indicated for use in patients undergoing cataract surgery or other ophthalmic treatment requiring penetrating arcuate cuts / incisions in the cornea.

The VICTUS Platform is an ophthalmic surgical femtosecond laser designed for cutting a penetrating arcuate cut of pre-selected depth, radius, opening angle, and position angle. The system works by first being programmed with the depth, radius, opening angle and position angle at which the penetrating arcuate cut is desired. The surgeon then fixates the eye with a sterile disposable PMMA contact lens (hereafter referred to as the Patient Interface) that is connected to the laser via a vacuum tube. Depths of -1200 to -120µm, radius of 1500 – 4750 µm, opening angles of 1-360°, and position angles of 0 - 359° are available.

Laser pulses are delivered through the sterile 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.

Indications for Use:

The VICTUS 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 penetrating arcuate cuts / incisions in the cornea in patients undergoing cataract surgery or other ophthalmic treatment requiring penetrating arcuate cuts / incisions in the cornea.

Technical Characteristics Comparison:

The design principle of the VICTUS Platform is fundamentally the same as the predicate devices. The VICTUS Platform mode of operation is the same as the previously cleared VICTUS Femtosecond Laser Platform cleared in K120426, iFS Laser System cleared in K113151, and the LenSx Laser System cleared in K101626, all of which deliver femtosecond pulses to produce a pattern of photodisruption to create cuts / separation in ophthalmic tissue. The VICTUS Platform delivers femtosecond pulses to produce a pattern of photodisruption for creation of penetrating arcuate cuts / incisions in the cornea, as do the predicate devices.

The means of fixation of the patient contact portion of the VICTUS Platform is substantially equivalent to that present in the VICTUS Femtosecond Laser Platform cleared in K120426, the Femtec Laser System for Anterior Capsulotomy cleared in K110427, iFS Laser System cleared in K113151, and the LenSx Laser cleared in K101626. All of these predicate systems use suction vacuum to affix a suction ring to the corneal surface prior to use.

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The VICTUS Platform mode of operation and the technology used to create the cutting action are similar or identical to these previously mentioned devices, and therefore substantially equivalent to these legally marketed predicate devices.

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 60601-1-4	Medical electrical equipment – Part 1-4: General requirements for safety; Collateral standard: Programmable electrical medical systems
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 devices in patients undergoing ophthalmic surgery or other treatment requiring penetrating arcuate cuts / incisions in the cornea. The VICTUS Femtosecond Laser Platform and the predicate devices therefore have similar performance profiles.

Non-Clinical Performance Data

A variety of test procedures were conducted to demonstrate the performance of the proposed VICTUS Platform in support of this premarket submission. 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). Scanning electronic microscopy has also been utilized to visually assess the results of the arcuate cuts / incisions procedures with the VICTUS Platform. The resulting micrographs are compared qualitatively with images obtained from the predicate devices.

The testing showed that laser-assisted arcuate cuts / incisions performed with the VICTUS Femtosecond Laser Platform resulted in highly reproducible and accurate rim depth, diameter, open angle, position angle, and centration.

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Postmarket Surveillance Clinical Review

A retrospective postmarket surveillance review was performed at a single site in Europe to compare manual arcuate incisions using a diamond blade to laser-assisted arcuate incisions using the VICTUS™ Platform. This review was conducted at a single clinical location, and all surgeries were performed by the same surgeon.

A total of 49 eyes in 34 subjects were included in the analysis. The mean age of the study population was 57.4 ± 11.7 years (range: 18 to 84 years). Twenty four (24) eyes received laser-assisted arcuate cuts, of which 11 received arcuate cuts alone and 13 received both arcuate cuts and cataract surgery. Twenty five (25) eyes received manual arcuate cuts, of which four received arcuate cuts alone and 21 received both arcuate cuts and cataract surgery. One adverse event was reported in the laser-assisted group, which was considered by the surgeon to not be related to the laser-assisted procedure.

The laser-assisted arcuate cuts procedure was shown to be comparable to the standard manual procedure when assessed for common clinical endpoints such as post-surgical loss of lines of best corrected distance visual acuity (BCDVA), post-surgical overall change in refraction, postoperative induced cylinder, adverse events, and serious adverse events.

The postmarket surveillance review data confirm that laser-assisted arcuate cuts are comparable to the standard manual procedure.

Basis for Determination of Substantial Equivalence:

The technological characteristics of the VICTUS Femtosecond Laser Platform are substantially equivalent to the technological characteristics of the VICTUS Femtosecond Laser Platform (K120426), the Femtec Laser System for Anterior Capsulotomy (K110427), iFS Laser System (K113151), the LenSx Laser (K101626).

The proposed additional indication for use of arcuate cuts / incisions for the VICTUS Femtosecond Laser Platform is very similar to the indications for use cleared for the iFS Femtosecond Laser in K113151 and for the LenSx Laser in K101426; both include arcuate corneal incisions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 8, 2013

Technolas Perfect Vision GmbH
% Ms. Betty M. Johnson
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PO Box 17190
Anaheim Hills, CA 92817

Re: K122386
Trade/Device Name: VICTUS Femtosecond Laser Platform
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Femtosecond Laser
Regulatory Class: Class II
Product Code: OOE, HQF
Dated: February 1, 2013
Received: February 4, 2013

Dear Ms. Johnson:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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 -S

Malvina B. Eydelman, M.D.
Director
Division of Opthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K122386

Device Name(s): VICTUS Femtosecond Laser Platform

Indications for Use:

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- the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea
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Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number K122386