JUL 15 2014

K140615: 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.

Date Prepared July 9, 2014

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Trade Name: VICTUS Femtosecond Laser Platform
Common Name: Ophthalmic Laser
Regulation Number 21 CFR 886.4390
Classification Name: Laser, Ophthalmic
Device Classification: Class II
Product Code OOE (Ophthalmic Femtosecond Laser)
HQC (Unit, Lens fragmentation)

Substantially Equivalent To:

510(k) Number	Product Trade Name	Current Manufacturer
K122386, K135234	VICTUS Femtosecond Laser Platform	Technolas Perfect Vision GmbH
K094052, K101626, K120732	LenSx Laser	LenSx, an Alcon company
K102727	LensAR Laser	LensAR Inc.

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 the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea and for anterior capsulotomy during cataract surgery (via K120426). In addition, the VICTUS has been cleared for patients undergoing cataract surgery or other ophthalmic treatment requiring penetrating arcuate cuts / incisions in the cornea (via K122386), and for corneal incisions (via K132534). This 510(k) expands the list of indications for use to include laser-assisted lens fragmentation during cataract surgery for nuclear cataracts.

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.

Safety margins are built into the software, including an anterior capsule safety margin of 500 μm, a posterior capsule safety margin of 700 μm, and a pupil safety margin of 500 μm. The graphical user interface is used to mark the anatomical boundaries and the software automatically calculates the safety margins. The safety margins are not modifiable by the end user.

The fundamental scientific technology remains the same as previously cleared for the VICTUS Femtosecond Laser Platform under K122386 and K132534.

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 cuts / incisions in the cornea in patients undergoing cataract surgery or other ophthalmic treatment requiring cuts / incisions in the cornea.
- laser-assisted lens fragmentation during cataract surgery for nuclear cataracts, not for fragmentation of posterior subcapsular (PSC) and cortical cataracts

Technical Characteristics Comparison:

The design principle and mode of operation of the VICTUS Platform is fundamentally the same as the VICTUS Platform cleared in K122386 and K132534, the LenSx Laser System cleared in K094052, K101626, and K120732, and the LensAR Laser cleared in K102727, all of which deliver femtosecond pulses to produce a pattern of photodisruption to fragment the crystalline lens. The VICTUS Platform delivers femtosecond pulses to produce a pattern of photodisruption

in the crystalline lens, as do the predicate devices.

The means of fixation of the patient contact portion of the VICTUS Platform is identical, and therefore substantially equivalent to that described in the VICTUS Femtosecond Laser Platform cleared in K122386 and K132534. The predicate system uses suction vacuum to affix a suction ring to the corneal surface prior to use. The vacuum suction and contact pressure are the same as the VICTUS Platform previously cleared in K132534 and therefore there are no changes in regards to the effect on intraocular pressure.

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.

Non-Clinical Performance Data

A variety of test procedures were conducted to assess 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. Three different materials were used for the bench performance testing: agarose gel, polyethylene terephthalate (PETG), and polymethyl methacrylate (PMMA). The testing showed that laser-assisted lens fragmentation performed with the VICTUS Femtosecond Laser Platform met the established acceptance criteria for lens fragmentation.

The non-clinical performance testing showed that laser-assisted lens fragmentation performed with the VICTUS Femtosecond Laser Platform resulted in highly reproducible and accurate treatments, including parameters such as upper and lower depth, cross angle, open angle, spot spacing, line spacing, and decentration.

Clinical Performance Data

Clinical performance was evaluated in a clinical study using the VICTUS Femtosecond Laser Platform (VICTUS) in cataract procedures. This study included evaluation of femtosecond laser-assisted lens fragmentation for nuclear cataracts as compared to manual methods for lens fragmentation for nuclear cataracts. This was a randomized, controlled, open, prospective, multi-center, multi-surgeon clinical study. Follow-up visits were conducted at one day, one week, and one month post-operatively.

Enrolled subjects were randomly assigned to one of two groups: Laser, which had lens fragmentation performed by the VICTUS device prior to phacoemulsification (treatment), and Manual, which had manual phacoemulsification.

One hundred thirty six (136) eyes of 110 subjects were included in the analysis (26 patients were treated bilaterally); 68 eyes were treated in the VICTUS study arm and 68 eyes in the standard treatment group. The mean age of the manual group over all cataract grades was 63.5 ± 10.4 years (range: 40 to 80 years), and the mean age of the laser group over all cataract grades was 62.3 ± 8.7 years (range: 45 to 83 years).

The demographics of the subjects included in the analysis of the clinical study are summarized in the following table.

Demographics—Subgroup Eyes (All Cataract Grades Combined)

Demographics	Number	%	Manual	Laser
NUMBER OF EYES				
Gender				
Female	77	56.6	40	37
Male	59	43.4	28	31
Race				
African-American	0	0	0	0
Asian	0	0	0	0
Caucasian	136	100%	68	68
Hispanic	0	0	0	0
Other	N/A	N/A	N/A	N/A
Age (Years)				
Mean (SD)			63.5 ± 10.4	62.3 ± 8.7
Minimum, Maximum			40, 80	45, 83
Study eye				
OD			36	27
OS			32	41

The types of cataracts included in the analysis of the study included nuclear cataracts with Grades 1-5, as noted in the following table.

Cataract Grade and Type

Parameter		Laser (N=68) n (%)	Manual (N=68) n (%)	Total (N=136) n (%)
Grade	1	16 (23.5)	16 (23.5)	32 (23.5)
	2	17 (25.0)	17 (25.0)	34 (25.0)
	3	14 (20.6)	14 (20.6)	28 (20.6)
	4	13 (19.1)	13 (19.1)	26 (19.1)
	5	8 (11.8)	8 (11.8)	16 (11.8)

Summary of Results

- Primary endpoint was met: Effective phacoemulsification time (EPT) in the laser group (pooled from all cataract grades) was lower than or equal to that in the manual group.
- Secondary endpoint was met: Less or equal adverse events in the laser group compared with the manual group.
- Other results:
    - Pre- and post-operative IOPs were similar between the VICTUS and manual groups at all time points during the study for the complete study group and when stratified by cataract grade.
    - Best corrected visual acuities (BCVDA) were similar between the VICTUS and manual groups at all time points during the study for the complete study group and also when stratified by cataract grade.
    - Slit lamp examinations in the laser group were consistent with the manual group at all time points for the complete study group and also when stratified by cataract grade.
    - The only intra-operative complications were two anterior capsule tears in the manual group; no other operative complications were recorded for either the manual or the laser group. The post-operative observation rates of corneal edema, flare and trace anterior chamber in the laser group were comparable to those in the manual group.
    - OCT images through the PI correlate well with biometric data obtained from OCT images for lens thickness and anterior chamber depth for the complete study group and also when stratified by cataract grade.
    - VICTUS OCT images were found to have a high level of precision for lens thickness (both pooled and stratified by cataract grade) and anterior chamber depth (pooled only).

Complications

Two intraoperative complications were reported during the study: two mild anterior capsular tears in the manual group. These complications were determined to be adverse events and are therefore also listed in the following Adverse Events section.

Adverse Events

During the study, a total of nine adverse events (5 events from 4 eyes in manual group and 4 events from 3 eyes in laser group) and serious adverse events (one in laser group and one in manual group) were observed. Seven events were judged as adverse events (three in the laser group and four in the manual group) and two as serious adverse events (one in laser group and one in manual group) were observed.

At one day, two events were documented in a single eye of one subject in the VICTUS group, cortex in the capsular bag (SAE) and increased IOP (AE). Another subject in the VICTUS group was found to have mild iritis at the one day visit (AE). The last subject in the VICTUS group was diagnosed with moderate iritis at the one visit (AE). All adverse events in the laser group were determined to be related to the cataract surgery and not to the use of the VICTUS Femtosecond Laser.

On the day of treatment, two mild anterior capsular tears were noted in the manual group (both AEs). One subject in the manual group was found to have moderate cystoid macular edema at the one month visit. The last subject in the manual group was diagnosed with iritis (SAE) and cystoid macular edema (AE) at an unscheduled visit that took place between the one week and the one month follow-up visit. All adverse events in the manual group were determined to be related to the cataract surgery.

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 (K122386 and K132534), the LenSx Laser (K094052, K101626, K120732).

The proposed additional indication for use of laser-assisted lens fragmentation during cataract surgery for the VICTUS Femtosecond Laser Platform is the same or very similar to that cleared for the LenSx Laser (K094052, K101626, and K120732), as well as for the LensAR Laser (K102727).

Overall, it can be concluded that the VICTUS can be successfully used for lens fragmentation during cataract surgery for nuclear cataracts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 15, 2014

Technolas Perfect Vision, GmbH
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Re: K140615
Trade/Device Name: VICTUS Femtosecond Laser Platform
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Codes: OOE, HQC
Dated: June 5, 2014
Received: June 9, 2014

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 contact 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. 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

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 STATEMENT

510(k) Number (if known): K140615

Device Name(s): VICTUS Femtosecond Laser Platform

Indications for Use:

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

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)

Charles Ehang -S
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