K131207

510(k) Summary

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

SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON, AND DATE SUMMARY PREPARED:

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OCT 09 2013

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c) Date of summary preparation: 10/03/2013

NAME OF DEVICE, INCLUDING TRADE NAME AND CLASSIFICATION NAME:

Trade/Proprietary Name: FEMTO LDV Z6 Femtosecond Surgical Laser
Common/Usual Name: Ophthalmic Laser
Classification Name: Laser, Ophthalmic
Classification Code: HQF

IDENTIFICATION OF THE PREDICATE DEVICE OR LEGALLY MARKETED DEVICE OR DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS BEING CLAIMED:

510(k) #	Trade Name	Manufacturer
K112154	FEMTO LDV Z-Generation Femtosecond Surgical Laser	SIE AG, Surgical Instrument Engineering

A DESCRIPTION OF THE DEVICE THAT IS THE SUBJECT OF THE 510(K), INCLUDING EXPLANATION OF HOW THE DEVICE FUNCTIONS, BASIC SCIENTIFIC CONCEPTS, SIGNIFICANT PHYSICAL AND PERFORMANCE CHARACTERISTICS (DESIGN, MATERIAL, PHYSICAL PROPERTIES):

Corneal dissection with the FEMTO LDV Z6 Femtosecond Surgical Laser is achieved through precise individual microphotodisruptions of tissue, created by tightly focused ultrashort optical pulses which are delivered through an applanation window assembly while fixating the eye under a vacuum.

STATEMENT OF INTENDED USE:

The FEMTO LDV Z6 Femtosecond Surgical Laser is an ophthalmic surgical laser indicated for the use in the creation of corneal incisions in patients undergoing LASIK surgery, tunnel creation for implantation of rings, pocket creation for implantation of corneal implants, lamellar keratoplasty, penetrating keratoplasty or other treatment requiring lamellar resection of the cornea at a varying depth with respect to the corneal surface.

In addition, the FEMTO LDV Z6 Surgical Laser is intended for use in patients undergoing cataract surgery for the creation of single-plane, multi-plane, partial thickness and full thickness cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.

STATEMENT OF HOW THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARE TO THOSE OF THE PREDICATE OR LEGALLY MARKETED DEVICE:

The latest release includes a new SW module, based on the existing software interface of FEMTO LDV Z6 and combination of existing cutting patterns. The module provides two new types of corneal incisions, i.e., Arcuate Corneal Incisions (arc) and Clear Corneal Incisions (CCI). The other two independent sub-modules SW (Safety System and Z-Safety System) remained unchanged. The SW architecture is the same as in the predecessor 510(k) K112154.

BRIEF SUMMARY OF NONCLINICAL TESTS AND RESULTS:

Results of the software validation and the in-vitro validation show that the design changes made to the device are substantially equivalent. The following is a summary of nonclinical tests and results:

- The software changes included all of the documentation, including validation, as per FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."
- An in-vitro validation was performed that demonstrated the accuracy and precision of the new 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 20993-0002

October 9, 2013

SIE AG, Surgical Instrument Engineering
% Mr. Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Inc.
33 Golden Eagle Lane
Littleton, CO 80127

Re: K131207
Trade Name: Femto LDV™ Z6 Femtosecond Surgical Laser
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF
Dated: August 22, 2013
Received: August 26, 2013

Dear Mr. Walls:

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, Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131207

Device Name: FEMTO LDV Z6 Femtosecond Surgical Laser

Indications for Use:

The FEMTO LDV Z6 Femtosecond Surgical Laser is an ophthalmic surgical laser indicated for the use in the creation of corneal incisions in patients undergoing LASIK surgery, tunnel creation for implantation of rings, pocket creation for implantation of corneal implants, lamellar keratoplasty, penetrating keratoplasty or other treatment requiring lamellar resection of the cornea at a varying depth with respect to the corneal surface.

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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)

Andrew Yang -S
2013.10.03
16:55:07 -04'00'

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) number: K131207