DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 23, 2015

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

Re: K150323
Trade/Device Name: FEMTO LDV™ Z8 Femtosecond Surgical Laser
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: OOE
Dated: September 18, 2015
Received: September 21, 2015

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 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 -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

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)*
K150323

Device Name
FEMTO LDV Z8 Femtosecond Surgical Laser

Indications for Use *(Describe)*

The FEMTO LDV™ Z8 Femtosecond Surgical Laser is an ophthalmic surgical laser intended for use in the creation of corneal incisions indicated for use 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™ Z8 Surgical Laser is intended for use in the creation of capsulotomy, phacofragmentation and the creation of single plane, multi-plane, arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure indicated for use in patients undergoing cataract surgery for removal of the crystalline lens.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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:

a) Applicant:

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c) Date of summary preparation:

February 2, 2015

NAME OF DEVICE, INCLUDING TRADE NAME AND CLASSIFICATION NAME:

Trade/Proprietary Name: FEMTO LDV™ Z8 Femtosecond Surgical Laser
Common/Usual Name: Ophthalmic Laser
Classification Name: Ophthalmic Femtosecond Laser
Classification Code(s): OOE

IDENTIFICATION OF THE PREDICATE DEVICE 0R LEGALLY MARKETED DEVICE OR DEVICES T0 WHICH SUBSTANTIAL EQUIVALENCE IS BEING CLAIMED:
510(k) # Trade Name Manufacturer

K131207 Ziemer LDV™ Z6
K121091 Optimedica® Catalys™ Precision Laser System

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):

The femtosecond laser has been used clinically in a variety of anterior segment applications in Ophthalmology for many years. These include creation of a corneal flap for laser in situ keratomileusis, refractive surgery, arcuate incisions for modifying corneal astigmatism, and keratoplasties for corneal transplantation. In the past years, femtosecond lasers have been

used in cataract surgery for capsulotomy creation, lens fragmentation, and corneal incision creation.

The design of the FEMTO LDV™ Z8 is based on the FDA cleared FEMTO LDV™ Z Models Femtosecond Surgical Lasers Z2-Z6, which already successfully treated more than 180'000 corneas in the USA and other countries. Including predecessor devices, about 3 million eyes have been treated on FEMTO LDV™ systems worldwide since 2006. The FEMTO LDV™ together with the Intralase iFS, which is a predicate device of the Z6, account for the biggest market share in terms of installed units and performed procedures.

The application of femtosecond lasers in the field of cataract surgery was achieved with extended focusing capabilities and improved visualization based on existing technologies.

Cataract surgery is a frequently performed procedure that includes several steps, such as creating corneal incisions; opening the anterior lens capsule, also referred to as the capsulotomy; emulsifying and removing the opacified crystalline lens; and subsequently inserting the intraocular lens (IOL).

In the past four years, femtosecond lasers have been used in cataract surgery for capsulotomy creation, lens fragmentation, clear corneal incision creation and arcuate incisions. Numerous studies have reported advantages of femtosecond laser over conventional phacoemulsification cataract surgery.

The studies described below have shown that capsulotomies created using the femtosecond laser were more accurate in size than those created by manual continuous curvilinear capsulorhexis (CCC) and that laser lens fragmentation significantly decreased the phacoemulsification power. The procedure was generally safe with low overall complication rates.

The capsulotomy provides the surgeon access to the capsular bag for fragmentation and removal of the natural lens and insertion of the IOL. The size of the remaining tissue should allow overlap between the capsule rim and the IOL haptic for correct IOL positioning. Intraocular lens alignment is particularly important with premium IOLs, such as accommodating, multifocal, and toric models. The most critical steps are for most surgeons still manual procedures. The most difficult manoeuvre to master is the creation of the continuous circular capsulorrhexis (CCC), which is performed by freehand tearing of the lens capsule and is therefore highly dependent on surgical skills and complicating factors. The procedure is prone to inconsistencies of size, shape and centration even in experienced hands. In the presence of many predisposing factors the level of difficulty and probability of creating a suboptimal CCC increases. These challenges and limitations stimulated the development of the femtosecond laser for laser anterior capsulotomy (LAC).

STATEMENT OF INTENDED USE:

The FEMTO LDV™ Z8 Femtosecond Surgical Laser is an ophthalmic surgical laser intended for use in the creation of corneal incisions indicated for use 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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STATEMENT OF HOW THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARE T0 THOSE OF THE PREDICATE OR LEGALLY MARKETED DEVICE:

The design of the FEMTO LDV™ Z8 Femtosecond Surgical Laser suction ring of the patient interfaces is the same as for the Ziemer LDV™ Z6. The attachment forces to the patient eye are the same. With the liquid patient interface, saline solutions are used as in the case of the predicate device Catalys™. Therefore, the patient interfaces of the FEMTO LDV™ Z8 Femtosecond Surgical Laser are substantially equivalent with the predicate devices and no new issues of safety and effectiveness arise.

Since the wavelength and the pulse width of the femto second laser pulses are the same, the underlying physical process is the same. The corneal software package and the user input of the FEMTO LDV™ Z8 Femtosecond Surgical Laser are identical to the Ziemer LDV™ Z6. Therefore, no new issues of safety and effectiveness are raised in corneal applications.

Also for cataract applications the wavelength and the pulse width of the femto second laser pulses are essentially the same. Therefore the underling physical process is the same. Compared to the Catalys™, the FEMTO LDV™ Z8 Femtosecond Surgical Laser uses smaller spots with lower pulse energies at higher repetition rates to achieve tissue dissection. The former K131207 showed that both regimes (larger pulse spacing at higher pulse energies vs. denser pulse spacing at lower pulse energies) are equivalent in the net effect of tissue separation along cut surfaces without raising new issues in terms of safety and effectiveness. Considering also that the FEMTO LDV™ Z8 Femtosecond Surgical Laser runs in the lens with same pulse energies or less than the Catalys™ no issues of safety and effectiveness arise in lens applications.

BRIEF SUMMARY OF NONCLINICAL TESTS AND RESULTS:
The FEMTO LDV™ Z8 Femtosecond Surgical Laser has undergone non-clinical testing and is in compliance with applicable safety standards. The FEMTO LDV™ Z8 Femtosecond Surgical Laser was found to perform equivalently to the predicate devices to achieve tissue dissection for corneal flap, rings, pockets, keratoplasty, corneal and arcuate incisions, capsulotomy, and lens fragmentation Thus, FEMTO LDV™ Z8 Femtosecond Surgical Laser and the predicate devices have similar safety, effectiveness and performance profiles.

TEST METHODS
The test methods performed to determine substantial equivalence included:

- Sterilization validation
- Shelf life testing
- Biocompatibility testing
- Safety tests according to IEC 60601-1, IEC 60601-1-2 and IEC 60825
- Design validation, including in-vitro performance testing
- Software validation