April 21, 2022

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

Re: K213559
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: March 10, 2022
Received: March 11, 2022

Dear Kevin 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. 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,

Anjana Jain, PhD
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)*

K213559

Device Name
FEMTO LDV™ Z8 Femtosecond Surgical Laser (modification to old model)

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

I. 510(k) Number K213559

II. SUBMITTER

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Date Prepared: April 21, 2022

III. DEVICE

Name of Device: FEMTO LDV™ Z8 Femtosecond Surgical Laser
Common or Usual Name: Ophthalmic Laser
Classification Name: Ophthalmic Femtosecond Laser
Regulatory Class: Class II
Product Code: OOE
Regulation Number: 886.4390

IV. PREDICATE DEVICE

The legally marketed (predicate) device to which we are claiming substantial equivalence is:
Device Name: FEMTO LDV™ Z8 Femtosecond Surgical Laser
510(k) Number: K150323

V. DEVICE DESCRIPTION

The FEMTO LDV™ Z8 Femtosecond Surgical Laser is a solid state femtosecond laser used in ophthalmology. It is used for producing cuts in ocular tissue and can be used in corneal and cataract surgery.

The Z8 produces femtosecond laser energy that is absorbed by the tissue, resulting in plasma formation. This plasma rapidly expands, creating a cavitation bubble separating the tissue. This process is known as photodisruption. Because of its very short pulse duration, femtosecond laser technology deploys low pulse energy that virtually eliminates damage peripheral to the incision site and can therefore be used to dissect tissue on a microscopic scale. Femtosecond laser systems may use closer spot spacing to overlap these cavitation regions, producing less tissue bridges.

The energy needed for photodisruption can be reduced with shorter pulse duration and smaller diameters of the spot. To achieve such a focused laser spot with a smaller diameter, a lens with a higher numerical aperture is required. Smaller spots enhance the accuracy and overall precision of cuts. The strategy of low pulse energy and small overlapping spots is employed by the FEMTO LDV technology, allowing the reduction of energy used.

The FEMTO LDV™ Z8 Femtosecond Surgical Laser system consists of the following functional units:

- Base Station (BS), integrating the Laser Cavity, Fixed Mirror Articulated Arm (FMAA), Power Supply, Computer, Touchscreen Monitor, Suction Unit, OCT Box, and Safety System (see Figure 1),
- Handpiece (HP) integrating the Cutting Lens and Topview Camera (see Figure 1),
- Disposable accessories (see Table 1)

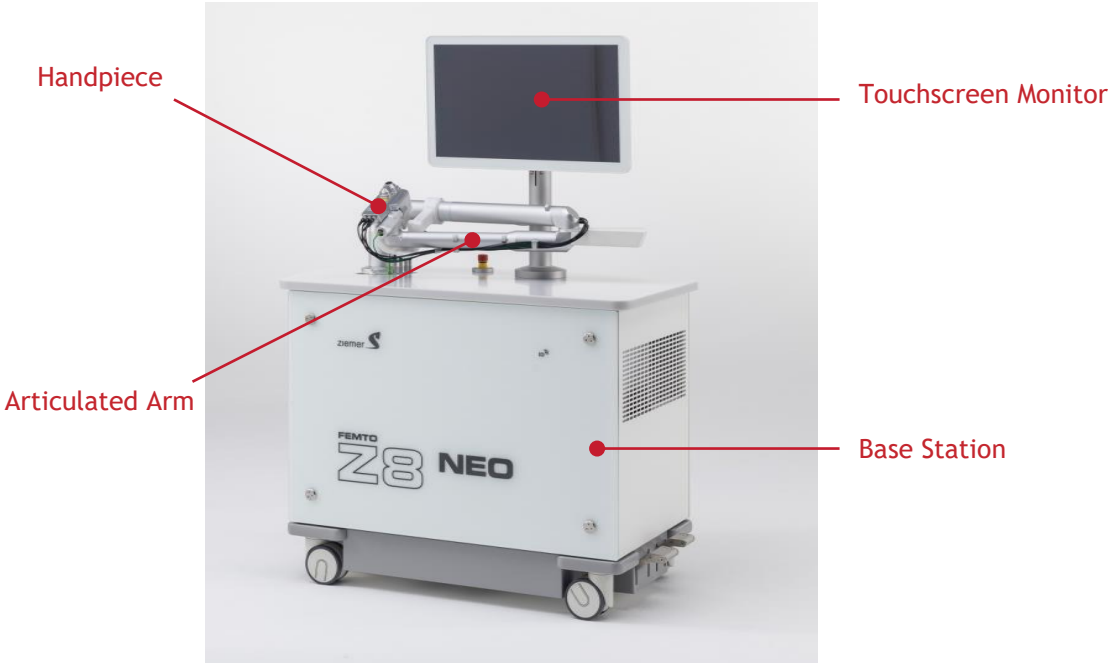

Figure 1: Main parts of FEMTO LDV™ Z8 Femtosecond Surgical Laser

The following components are mandatory accessories for the FEMTO LDV™ Z8 Femtosecond Surgical Laser:

Table 1: Accessories of FEMTO LDV™ Z8 Femtosecond Surgical Laser

Accessory	Description
Procedure Pack (PP) with Liquid Patient Interface (LPI) for Cataract surgery.	The PP is sterile, single use kit composed of a casing, a suction tubing and a liquid patient interface which get connected with the Handpiece and enable a sterile interface to the human eye via vacuum. A set of drapes for base station and articulated arm completes the PP for Cataract surgery.
Procedure Pack (PP) with Applanating Patient Interface (API) for Corneal surgery	The PP is sterile, single use kit composed of a casing, a suction tubing and an applanating patient interface which get connected with the Handpiece and enable a sterile interface to the human eye via vacuum. A base station drape completes the PP for Corneal surgery.

VI. INDICATIONS FOR USE

The following indications for use remain unchanged from those previously cleared via K150323:

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, FEMTO LDV™ Z8 Femtosecond 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.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

Modifications of the cleared device described in this 510(k) are the following ones:

1. Second source Laser Cavities: Two Laser cavities with identical requirement and function are introduced as an alternate (second source) for the existing one.

2. Improved Power Sensors: By minor adjustments to the optic-mechanical design the sensor's adjustment tolerance is improved.

3. Structured LEW[1]/LAF: By introducing a 3-dimensional structure in the LEW, the reliability of the zero point determination for the OCT picture is significantly increased.

4. Improved Vacuum System: The vacuum design was slightly changed for a more reliable and robust vacuum check.

5. SLIM Handpiece and SLIM Procedure Packs: The geometry of the Handpiece (HP) and of the Procedure Packs (PP) was slightly changed to better fit the anatomy of patients with thicker eyelids. In addition raw material trade name changes were introduced.

6. Small Esthetic changes: Changes to color and design of monitor, table and panels.

7. Latest software release: The changes listed above have been incorporated into various SW releases. As a consequence we decided to submit the latest software version.

A comparison of the technological characteristics is listed in Table 2:

[1] LEW is an abbreviation for „Laser Exit Window". In the R&D documentation unfortunately the German term is used LAF („Laser Austritts-Fenster") more commonly.

Table 2: Comparison between the cleared and the proposed device

Characteristics	Cleared Device	Proposed Device	Difference
General			
510(k) No	K150323	K213559	n/a
Classification	Class II, OOE	Class II, OOE	No difference
Intended Use & Indication for 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. 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.	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.	No difference
FEMTO LDV™ Z8 Femtosecond Surgical Laser Device			
Base Station footprint	102 cm (L) x 56 cm (W) x 77 cm (H).	102 cm (L) x 53 cm (W) x 78 cm (H).	Minor difference: Because of the changed dimension and shape of the table plate, the footprint has changed slightly.
Base station design	Black panels	White panels and changed table plate	Minor difference: - Color changes - Table plate was slightly changed in dimension and shape for better usability
Touchscreen Monitor	Black Touchscreen Monitor with straight edges	White Touchscreen Monitor with round edges	Minor difference: Touch screen monitor (from a different supplier)

Characteristics	Cleared Device	Proposed Device	Difference
			with same functionality but different color and round edges.
Power Sensors	Power sensor 4 & 5	Power sensor 4 & 5 with Ulbricht sphere	Minor difference: Slight design modification for better reliability.
Suction Unit (Vacuum System)	Single tube system	Twin tube system	Minor difference: Different connector and tube system for compatibility with Twin tube PP (see below).
Handpiece	Handpiece HP 6.3	Handpiece HP 6.4	Minor difference: - Slightly changed geometry - Adapted design of laser exit window.
Operating Principle	Photodisruption	Photodisruption	No difference
Laser Parameters			
Laser Type	Solid state mode locked, diode pumped	Solid state mode locked, diode pumped	Minor difference: Second source laser cavities with identical requirement and function.
Laser wavelength	1020 - 1060nm	1020-1060nm	No difference
Pulse with	200-500 fs	200-500 fs	No difference
Max Pulse Energy	< 6 µJ	< 6 µJ	No difference
Max Pulse Frequency	< 10 MHz with ±10% tolerance	< 10 MHz with ±10% tolerance	No difference
Spot Size	< 2 µm	< 2 µm	No difference
Software	LASIK Corneal Incisions including CCI[2] and ARC[3] Pocket	LASIK Corneal Incisions including CCI and ARC Pocket	Minor difference: Bug fixes and improvements that did not require a 510(k) for each single change according to the

[2] Clear Corneal Incision

[3] Arcuate Incision

Characteristics	Cleared Device	Proposed Device	Difference
	Ring Keratoplasty including LKP[4], PKP[5] and KeraKlear Cataract including CAPS[6] and LF[7]	Ring Keratoplasty including LKP, DALK, PKP, Liquid PKP and KeraKlear Cataract including CAPS, LF, CCI and ARC Cataract Training Surgery Report Tool	Guideline "*Deciding When to Submit a 510(k) for a Software Change to an Existing Device dated October 25, 2017".*
Material	The device does not contain or dispense any medicinal substances, tissues of animal origins, or any other materials requiring special considerations.	The device does not contain or dispense any medicinal substances, tissues of animal origins, or any other materials requiring special considerations.	No difference
Packaging	The device is packed in a wooden crate:	The device is packed in a wooden crate:	No difference
FEMTO LDV™ Z8 Femtosecond Surgical Laser PP			
Composition			
Casing	Casing	SLIM Casing	Minor difference: - Slight geometry modifications - Slight Material change: Same bulk material, but different trade name version
Patient Interface	Applanating patient interface Liquid patient interface	SLIM Applanating patient interface SLIM Liquid patient interface	Minor difference: - Slight geometry modifications - Slight Material change: Same bulk material, but different trade name version
Suction Tubing	Suction tubing with one tube	Suction tubing with two tubes	Minor difference: Two tubes instead of one and different connector without any material change.
Drape Set or Drape	PP Cataract: Drape set consisting of four drapes. PP Cornea: One base station drape.	PP Cataract SLIM: Drape set consisting of four drapes. PP Cornea SLIM: One base station drape.	No difference

[4] Lamellar Keratoplasty
[5] Penetrating Keratoplasty
[6] Capsulotomy
[7] Lens Fragmentation

Characteristics	Cleared Device	Proposed Device	Difference
Packaging			
Primary Packaging	PP Cornea: Blister PP Cataract: Blister and pouch with drape set	PP Cornea SLIM: Blister PP Cataract SLIM: Blister and pouch with drape set	No difference
Secondary Packaging	PP Cornea: Sales Unit (Box of 10) PP Cataract: Sales Unit (Box of 10)	PP Cornea SLIM: Sales Unit (Box of 10) PP Cataract SLIM: Sales Unit (Box of 10)	No difference
Sterilization Method	EO (Ethylene oxide) Sterilization	EO (Ethylene oxide) Sterilization	No difference
Shelf life	3 years	3 years	No difference

The other components of the FEMTO LDV™ Z8 Femtosecond Surgical Laser as Fixed Mirror Articulated Arm, Power Supply, Computer, OCT Box and Safety System did not change.

All changes are minor and have no effect on safety or effectiveness; therefore, these two devices are considered substantially equivalent.

VIII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Non-clinical testing

Safety testing and electromagnetic compatibility (EMC)
The following safety and EMC tests were conducted with the modified device including the changes above:

- IEC 60601-1-2
- IEC 60601-1
- IEC 60601-1-6
- IEC 60601-1-2-22
- IEC 60825-1

Biocompatibility, Cytotoxicity, Microbiological and Sterilization testing
A risk-based decision was made to test only in vitro for EO/ECH residuals and cytotoxicity due to the only minor material and geometry adjustments of the SLIM Procedure Packs. A repetition of in vivo tests was deliberately omitted, as these had already been extensively tested with the substantially equivalent predecessor products.
Although primary packaging for the modified SLIM Procedure Packs are the same as for the current 510(k)-cleared Procedure Packs, the sterilization validation was retested. The outcome of the re-validation showed that all acceptance criteria were achieved and proved compliance with ISO 11135:2014.

Software Verification and Validation testing
Every change was verified and validated according to ISO 62304 and documentation was provided as recommended by FDA's *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".*

Bench Testing
All bench testing results demonstrated equivalent performance between the modified and the cleared device according to the changes summarized in chapter VI.COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES. The bench testing comprises the following tests:

- Sterilization validation of the disposable accessories
- Shelf-life testing of the disposable accessories
- Verification of the different Resection Geometries
- System verification

Clinical Studies

The changes described in section IV did not require clinical performance data to demonstrate substantial equivalence to the predicate device.

VIII. CONCLUSIONS

The modified FEMTO LDV™ Z8 Femtosecond Surgical Laser is substantially equivalent to the cleared FEMTO LDV™ Z8 Femtosecond Surgical Laser as all changes do not affect safety and effectiveness.