DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

SIE AG, Surgical Instrument Engineering
c/o Kevin Walls, RAC
Regulatory Insight, Inc.
5401 S. Cottonwood Ct.
Greenwood Village,
CO 80121

MAR 15 2012

Re: K112154
Trade/Device Name: Femto LDVTM Z-Generation Femtosecond Surgical Laser
models FEMTO LDV Z2, FEMTO LDV Z4 and FEMTO LDV Z6
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: 2
Product Code: HQF
Dated: February 25, 2012
Received: February 27, 2012

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 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 Alexander

for

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

Enclosure

Indications for Use

510(k) Number (if known): K112154

Device Name: FEMTO LDV Z-Generation Femtosecond Surgical Laser (FEMTO LDV Z2)

Indications for Use:

The FEMTO LDV Z2 Femtosecond Surgical Laser is an ophthalmic surgical laser indicated for use in the creation of corneal incisions in patients undergoing LASIK surgery or other treatment requiring lamellar resection of the cornea at constant depth relative to the corneal surface.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K112154

Indications for Use

510(k) Number (if known): K112154

Device Name: FEMTO LDV Z-Generation Femtosecond Surgical Laser (FEMTO LDV Z4)

Indications for Use:

The FEMTO LDV Z4 Femtosecond Surgical Laser is an ophthalmic surgical laser indicated for 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 or other treatment requiring lamellar resection of the cornea at a varying depth with respect to the corneal surface that does not enclose a volume of the cornea.

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)

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Nose and Throat Devices

510(k) Number K112154

Indications for Use

510(k) Number (if known): K112154

Device Name: FEMTO LDV Z-Generation Femtosecond Surgical Laser (FEMTO LDV Z6)

Indications for Use:

The FEMTO LDV Z6 Femtosecond Surgical Laser is an ophthalmic surgical laser indicated for 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 the corneal surface that may enclose a volume of the cornea.

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)

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