September 22, 2022

Laser Engineering, Inc.
Laurie Dobbs
Quality Assurance
475 Metroplex Drive Suite 401
Nashville, Tennessee 37211

Re: K211605
Trade/Device Name: Dual Switch
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: May 20, 2021
Received: May 25, 2021

Dear Laurie Dobbs:

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,

Jianting Wang
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K211605

Device Name
Aurora MD-30 CO2 Laser

Indications for Use *(Describe)*
The intended use for the Aurora MD-30 CO2 Laser is for the vaporization, incision, excision, ablation, or photocaogulation of soft tissue in the surgical specialties of ENT, Gynecology, Laparoscopic Surgery including GYN Laparoscopy, Aesthetic Surgery, Dental and Oral Surgery, Neurosurgery, Orthopedics, General Surgery and Podiatry.

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

In accordance with 21 CFR 807.92 the 510(k) Summary for the Laser Engineering Aurora MD-30 CO_2 Laser is provided below.

Submitter:	Laser Engineering 475 Metroplex Drive, Suite 401 Nashville, TN 37211 Tel: (615) 739-5418
Contact Person:	Laurie Dobbs Management Representative Email: l.dobbs@americansurg.com
Date Prepared:	8-22-2022
Device Proprietary Name:	Aurora MD-30 CO_2 Laser
Device Common Name:	Aurora MD-30 CO_2 Laser
Classification Name:	Powered Laser Surgical Instrument
Classification Regulation:	21 CFR 878.4810
Product Code:	GEX
Predicate Device Name(s):	MD CO_2 Surgical Laser System Dual Switch
Predicate Manufacturer:	Laser Engineering
Predicate 510k(s):	K905676, K951812

Device Description:
The Aurora MD-30 CO_2 Laser is a Carbon Dioxide (CO_2) surgical laser system that can deliver up to 30 watts of laser power in the 11.2-micron range in the infrared. The laser can be used in a variety of surgical specialties. The power can be selectively delivered either through an articulated arm or through infrared fibers using an integrated electromechanically controlled optical switch that directs the beam either vertically into the articulated arm or at an angle into the fiber. The laser can operate in either continuous wave, pulsed or super pulse modes. It can deliver laser power down to ½ a watt and can operate down to millisecond pulse widths. The system also has a visible aiming beam to indicate where the CO_2 laser beam will be delivered.

The laser system has a 12inch highly visible color touchscreen to control the laser. It consists of a small self-contained floor standing, easily moveable console which contains the laser and all associated electronics and delivery systems.

The Aurora MD-30 CO_2 Laser has an integrated dual switch adapter that is operated by an electrical linear motor and controlled by the console. The switch allows the user to redirect the laser beam from the articulated arm to the fiber as desired.

Indications for Use:
The intended use for the Aurora MD-30 CO2 Laser is for the vaporization, incision, excision, ablation, or photocoagulation of soft tissue in the surgical specialties of ENT, Gynecology, Laparoscopic Surgery including GYN Laparoscopy, Aesthetic Surgery, Dental and Oral Surgery, Neurosurgery, Orthopedics, General Surgery and Podiatry.

Technological Characteristics Compared to Predicate Device

Product	Ultrapulse Laser	MD CO_2 Laser & Dual Switch	Aurora MD-30 CO_2 laser	
510(K) Number	K951812	K905676	K211605	
Manufacturer	Coherent /Lumenis	Laser Engineering, Inc	Laser Engineering, Inc	
Laser Type	CO_2 Gas Laser	CO_2 Gas Laser	CO_2 Gas Laser	Same
Operating Wavelengths	11.1 Microns	10.6 Microns	11.2 Microns	Similar
Output Power	0.5 to 45 Watts	0.5 to 30 Watts	0.5 to 30 Watts	Similar
Laser Beam Mode	TEM00	TEM00	TEM00	Same

Operating Modes	Continuous or Pulsed	Continuous or Pulsed	Continuous or Pulsed	Same
Pulse Widths	0.01 to 1.0 Sec	0.05 to 1.0 Sec	0.05 to 1.0 Sec	Same/Similar
Control method	Computer and Touchscreen	Computer and Touchscreen	Computer and Touchscreen	Same
Aiming Beam Power	5 Milliwatts	5 Milliwatts	5 Milliwatts	Same
Laser Power Delivery System	Articulated arm	Articulated arm or Hollow Waveguide	Articulated arm or Hollow Waveguide	Same/Similar
Beam Switching Method	n/a	Manual Switch	Electro-mechanical Linear Motor	Different
Output Indicator	LEDs	LEDs	LEDs	Same

The proposed device's output parameters are either the same or similar as output parameters from the predicate devices. The proposed device uses an electro-mechanical motor rather than a manual switch to divert the output beam. This modification does not raise new types of questions regarding the safety and efficacy of the device, and the proposed device's beam diverter has been tested to demonstrate that it can be used safely and effectively for the proposed indications for use.

Non-Clinical Testing Summary

Test Standard	Test Description	Test Report	Test Results
IEC 60601-1:2005 Ed.3+A1;C1:2014	Medical Electrical Equipment – Part 1: General Requirements For Basic Safety And Essential Performance	104954641BOX-002	PASS
IEC 60601-1-6:2010Ed.3+A1	Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability	104954641BOX-003	PASS
IEC 60601-2-22:2019 Ed.4	Medical Electrical Equipment - Part 2-22: Particular Requirements for Basic Safety and Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment	104954641BOX-004	PASS
IEC 60601-1-2:2014Ed.4	Medical Electrical Equipment - Part 1-2: General Requirements For Safety - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests	104954641BOX-017	PASS

Clinical Testing:
NA - Clinical testing was not required to establish substantial equivalence

Conclusions:
The proposed device utilizes technological characteristics that are the same or are similar to the predicate devices. The proposed device's technological characteristics do not raise new types of questions regarding safety and effectiveness, and performance testing conducted supports that the device can be used safety and effectively for the proposed indications for use above. Based on the comparison and analysis of data within this 510(k) submission, the proposed device is considered to be Substantially Equivalent (SE) to the predicate devices.