July 16, 2020

Lumenis Ltd.
Shlomit Segman
Senior Manager RA
6 Hakidma Street PO Box 240
Yokneam, 2069204
Israel

Re: K201663
Trade/Device Name: AcuPulse W CO2 Laser Systems, Delivery Devices and Accessories
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: June 15, 2020
Received: June 19, 2020

Dear Shlomit Segman:

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,

Colin Kejing Chen
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201663

Device Name
Lumenis AcuPulse W CO2 Laser System, Delivery Devices and Accessories

Indications for Use *(Describe)*
Lumenis AcuPulse W CO2 Laser System, Delivery Devices and Accessories is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynaecology, neurosurgery, orthopaedics, general and thoracic surgery. The use with the scanning unit is indicated for ablative skin resurfacing.

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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K201663

510(k) SUMMARY

The Lumenis AcuPulse W Laser System, Delivery Devices and Accessories

Applicant Name: Lumenis Ltd.
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Fax: +972-4-9599198
Email:Shlomit.Segman@lumenis.com

Date Prepared: 15 June 2020

Trade Name: The Lumenis AcuPulse W Laser System, Delivery Devices and Accessories

Classification Name: Powered laser surgical instrument

Product Code: GEX

Device Class: Class II

Regulation Number: 21 CFR 878.4810

Panel: General & Plastic Surgery

Predicate Devices: AcuPulse Family of CO_2 Lasers system (K180597)

Intended Use/ Indications for Use:
Lumenis AcuPulse W CO_2 Laser System, Delivery Devices and Accessories is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynaecology, neurosurgery, orthopaedics, general and thoracic surgery. The use with the scanning unit is indicated for ablative skin resurfacing.

Device Description:

The subject AcuPulse W system is a new scaled-down version of the recently FDA cleared Lumenis AcuPulse CO_2 Laser System, Delivery Devices and Accessories under K180597. It is based on the following hardware components in the AcuPulse:

- A Laser Console with a Free Beam Port to which an articulated arm attached.
  - Identical to the AcuPulse, the Laser Console of the AcuPulse W System houses the laser tube and optical system, the laser power source, console electronics, laser output ports, cooling system, purge air pump, control components (including touch screen, emergency stop button) and rear connector panel.

- An articulated arm to guide laser output via a set of folding mirrors to the connected accessory for delivery of laser energy to the tissue.

- A footswitch to activate the laser treatment beam and allow the selected laser energy to be transmitted via the delivery device to the target location.

- A variety of Free Beam Delivery Device and accessories.

The AcuPulse and AcuPulse W systems have the same proprietary software, which is embedded in the Main Controller, Peripheral Controller units and PC. The differences between the two are the enabled or disabled software features, through a hardware key (HASP dongle), that reflects the capabilities of each laser system or the particular configuration of a given system. Importantly, both systems use the same Software version, which was already validated, verified and submitted under K180597.

The AcuPulse W is offered with a subset of the previously cleared AcuPulse Handpieces/Tips that connect to the articulated arm or/and scanners for controlled delivery of laser energy to the target tissue. In addition, Lumenis is adding a Titanium (Ti-6Al-4V) 90° Side-firing Handpiece design. Like the cleared handpieces, it has multiple uses. The 90° Side-firing handpiece connects to the cleared AcuScan 120 Microscanner through two adaptors (a Handpiece Adapter and Third Lens Adapter) for delivery of laser energy. The 90° Side-firing handpiece is comprised of the following components:

- Handpiece Adapter
- Tip (Standard or Fine)
- Limiter ring (Standard or Fine)

This handpiece is based on the same technology and principles of operation of the cleared CO_2 delivery devices and its introduction does not raise any new questions of safety and/or efficacy.

Substantial Equivalence

The intended use of the AcuPulse W System is a shortened version of the cleared AcuPulse, with the changes to reflect the reduced options proposed for the AcuPulse W System and to follow the format that we have noted for the reference, competing device DEKA SmartXide2 (K133895) and other cleared CO_2 laser systems (see also K101555, K063001, K160312 and K172096).

In addition, the same technological characteristics and principles of operation apply for all laser systems, Delivery Devices and accessories.

Design verification processes were performed as a result of this risk analysis assessment to verify that no different questions of safety and effectiveness have been raised due to the modifications introduced. The test methods are essentially the same as those used to support to the clearance of the AcuPulse CO_2 Laser System, Delivery Devices and Accessories (K082809, K100415, K180597).
The following activities were performed:

- Risk analysis (ISO 14971)
- Electrical and laser safety and electromagnetic compatibility testing as required to conform to performance standards as follows:
    - IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
    - IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- requirements and tests
    - IEC 60825-1: Safety of laser Products-Part 1: Equipment classification and requirements
    - IEC 60601-2-22: Medical electrical equipment- part 2: particular requirements for the safety of diagnostic and therapeutic laser equipment.
- 90° Side-firing Handpiece testing demonstrating demonstrate that the accessory together with the AcuPulse W system performs in compliance with their specifications and requirements
- 90° Side-firing Handpiece Cleaning (AAMI TIR 30) and sterilization validation activities (ISO 17665-1)
- 90° Side-firing Handpiece Biocompatibility of materials (ISO 10993)

Test results indicated that the new configuration AcuPulse W CO_2 Laser System, Delivery Devices and accessories perform in accordance with its requirements and specifications similarly to its predicate device. Consequently, Lumenis Ltd. believes that AcuPulse W CO_2 Laser System, Delivery Devices and Accessories is substantially equivalent to the cleared predicate and it does not raise any different questions of safety and/or effectiveness.