October 22, 2020

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

Re: K202428
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: August 19, 2020
Received: August 25, 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,

Purva Pandya
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)*

K202428

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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K202428 510(k) SUMMARY

The Modified Lumenis AcuPulse W Laser System, Delivery Devices and Accessories

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Date Prepared: 19 August 2020

Trade Name: 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 W CO_2 Lasers System Delivery Devices and Accessories (K201663)

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 AcuPulse W system (recently cleared under K201663) is a scaled-down version of the cleared Lumenis Family of AcuPulse CO_2 Laser System, Delivery Devices and Accessories under K180597. The modified AcuPulse W, identically to its predicate (K201663) is comprised of the following main functional components:

- A Laser Console with a Free Beam Port to which an articulated arm is attached
- 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 modified AcuPulse W and the cleared AcuPulse W (K201663) systems have the same proprietary software, which is embedded in the Main Controller, Peripheral Controller units and PC. Importantly, both systems use the same Software version, which was already validated, verified and submitted under K201663. Also, no changes to the Hardware were made to the system.

The AcuPulse W is offered with previously cleared AcuPulse Handpieces/Tips that connect to the articulated arm or/and scanners for controlled delivery of laser energy to the target tissue. Among them, the cleared 90° Side-firing Handpiece (K201663) connects to the 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 (cleared under K201663)
- Tip:
    - Multiuse Standard Focus Tip (cleared under K201663)
    - Multiuse Fine Focus Tip (cleared under (K201663)
    - Disposable Standard Focus Tip (subject of this submission)
    - Disposable Fine Focus Tip ((subject of this submission)
- Limiter ring (cleared under K201663)

In this submission, Lumenis is introducing a disposable configuration of the 90° Side-firing Handpiece Tips in addition to the already cleared multiuse tips to respond to the increased market demand of disposable accessories for reducing the occurrence of treatment acquired infections. These 90° Side-firing Handpiece disposable tips are single use tips, packaged and EO sterilized, similarly to Lumenis devices previously cleared and used with the cleared AcuPulse Family of CO2 Lasers (K100384 and K130164).

Substantial Equivalence
The intended use of the Modified AcuPulse W System is identical to the cleared AcuPulse W System (K201663). The addition of the disposable configuration of 90° Side-firing handpiece Tips does not affect the intended use or mode of operation.

In addition, the system console and the rest of the accessories remained unchanged, i.e., no change to the software, hardware and system specifications, maintaining the identical technological characteristics and principles of operation as the cleared AcuPulse W laser system, 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 addition of this disposable configuration of 90° Side-firing handpiece Tips. The test methods are essentially the same as those used to support to the clearance of the AcuPulse W and other Lumenis cleared sterile and non-sterile Delivery Devices and Accessories (K082809, K100415, K180597, K201663).

The following activities were performed:

- Risk analysis per ISO 14971
- Electrical safety testing as required to conform to IEC 60601-1 standard.
- Performance verification and validation activities were conducted to evaluate that the 90° Side-firing Handpiece with the new disposable configuration of Tips performs according to its specifications.
- EO sterilization and Shelf-life validation activities for the new disposable configuration of the 90° Side-firing Handpiece Tips were conducted by external laboratories. The test methods were essentially the same as those used to support the clearance of the cleared Sterile Fibers used with the AcuPulse Family of CO2 Laser System (cleared under K100384 and K130164), Testing results demonstrate compliance with ISO 11607, ISO 11135-1, and ISO 10993.
- The biocompatibility of the new disposable configuration of the 90° Side-firing Handpiece Tips was evaluated to verify that the contact materials, identical to materials present in cleared predicate accessories (K100415), comply with ISO 10993 and FDA's guidance, Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing with a Risk Management Process."

Test results indicated that the AcuPulse W with the 90° Side-firing Handpiece equipped with the new configuration of disposable tips performs in accordance with its requirements and specifications similarly to its predicate device. Consequently, Lumenis Ltd. believes that the modified 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.