June 21, 2022

Lumenis Inc.
% Kathy Maynor
Regulatory Consultant
Kathy Maynor
26 Rebecca Ct
Homosassa, Florida 34446

Re: K211979
Trade/Device Name: Lumenis Y&R Laser System
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, ONG
Dated: May 6, 2022
Received: May 9, 2022

Dear Kathy Maynor:

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)*
K211979

Device Name

Lumenis YandR Laser System

Indications for Use *(Describe)*
The YandR System, handpiece and accessories are intended for dermatological procedures requiring the coagulation of soft tissue as follows:

1410 nm Indications for Use:
• Fractional skin resurfacing procedures

1927 nm Indications for Use
• Fractional skin resurfacing procedures

LPTT (Polytherapy) application of 1410 nm and 1927 nm simultaneously
• Fractional skin resurfacing procedures

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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Section 8 510(k) Summary

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

I. Submitter Information [21 CFR 807.92(a) (1)]

Owner Name	Lumenis Inc.
Address	1870 Milestone Dr. Salt Lake City, UT 84104
Contact Person	Kathy Maynor Regulatory Consultant Email: kmaynor77@gmail.com Phone: 352-586-3113 (cell)
Summary Preparation Date	June 21, 2022

II. Name of device [21 CFR 807.92 (a) (2)]

Trade or Proprietary Name	The Lumenis Y&R Laser System		
Common Device Name(s), Regulatory Class and Classification Name	**Product Code(s)**	**Classification Panel**	**Regulation**
Powered Laser Surgical Instrument Class II Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology	GEX ONG	General & Plastic Surgery Panel, 79 (SU) General & Plastic Surgery Panel, 79 (SU)	§ 21 CFR 878.4810 § 21 CFR 878.4810

III. Predicate Devices [21 CFR 807.92(a) (3)]

510(k) #	**Trade Name**	**Product Code**
K063808	Fraxel IV SR Laser System and Accessories	GEX
K130193	Fraxel Dual 1550/1927 nm	GEX

IV. Device Description [21 CFR 807.92(a) (4)]

The Lumenis YandR Laser System consists of:

- System console (contains the laser diodes, the system software, power supply, and various other electronic and mechanical parts)
- Operator control panel with touch-screen technology (GUI)
- NAFR handpiece and single-use removable tips
- Footswitch and other laser safety accessories

The non-ablative fractional NAFR handpiece emits two wavelengths – 1410nm and 1927nm. The 1410nm and 1927nm laser diode modules are located in the console and are coupled into the single handpiece via fiber optics. Through the GUI screen on the system console, the user can select either fractional wavelength, or a combination of both.

V. Intended use and Indications for Use [21 CFR 807.92(a)]

The YandR System, handpiece and accessories are intended for dermatological procedures requiring the coagulation of soft tissue as follows:

1410 nm Indications for Use
- Fractional skin resurfacing procedures

1927 nm Indications for Use
- Fractional skin resurfacing procedures

LPTT (Laser Polytherapy Treatment) application of 1410 nm and 1927 nm simultaneously
- Fractional skin resurfacing procedures.

The IFU for the YandR system and the IFU for the predicate Fraxel systems differ in that the IFU for the YandR systems contains instructions for the clinical use of the LPTT (laser polytherapy) mode where the 1410 nm and 1927 nm wavelengths are fired simultaneously, resulting in spots of each wavelength placed next to each other on the skin. This mode is not present in the predicate Fraxel lasers. The IFU for the YandR system also contains only instructions for fractional skin resurfacing procedures.

The laser polytherapy mode is indicated for fractional skin resurfacing procedures, as are the predicate Fraxel lasers. To ensure that the use of the LPTT mode for these wavelengths is comparable to the use of the single wavelengths independently, Lumenis performed a histology study that showed substantially equivalent results when the LPTT dual wavelength mode was compared to the single wavelength mode. The technical differences do not affect the safety or effectiveness of the system.

VI. Summary of technological characteristics of the device compared to the predicates [21 CFR 807.92(a)(6)]

The technical characteristics for the Lumenis YandR are substantially equivalent to the predicate devices. The mode of operation is the same as the predicates.

The non-ablative 1410 nm wavelength has some differences in power and tip size when compared to the predicate Fraxel laser (K063808), but the histology study showed the expected results for wound healing. The wavelength, maximum pulse energy per microbeam, pulse width, repetition rate and microbeam spot size are either the same or within the range of the cleared predicate device (K063808).

The non-ablative 1927 nm wavelength has some differences in power, pulse repetition rate and tip size when compared to the predicate Fraxel device (K130193), but the histology showed the expected results for wound healing. The wavelength, maximum pulse energy per microbeam, pulse width, repetition rate and microbeam spot size are the same or within the range of the cleared predicate device (K130193).

Both the YandR system and the predicate Fraxel devices contain a velocity sensor that adjusts laser delivery to control the spot density independent of variations in speed.

The YandR system contains an additional operational mode – the LPTT (laser polytherapy treatment). This mode is not present in the predicate Fraxel devices, and it allows the 1410 nm and 1927 nm laser beams to be fired simultaneously in a manner which places the resulting laser spots next to each other. Lumenis did perform histology testing to justify the technical differences and the use of the LPTT mode to support substantial equivalence.

VII. Performance Testing [21 CFR 807.92(b)(1)]

IEC 60601-1 Medical Electrical Equipment-Part 1: General Requirements for safety
IEC 60601-1-2 Medical Electrical Equipment 1-2 General Requirements for basic safety and essential performance – Electromagnetic Compatibility
IEC 60601-2-22 Medical Electrical Equipment-Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
IEC 60825-1 Safety of laser products-Part 1: Equipment Classification, requirements and user's guide
ISO 10993-1 Biological evaluation of medical devices -- Part 1
IEC 62304 Medical Device Software
ISO 14971 Risk Analysis

In addition, software verification and performance validation testing were performed.

Lumenis Inc. also performed histology testing on porcine animals. The purpose of this study was to determine the existence, physical extent, and wound healing response of

microthermal zones (MTZs) produced by the Y&R fractional laser device, to verify the non-ablative nature of the device, and complete wound healing were examined at different time points post-treatment.

Lumenis performed histology testing on porcine animals for all three treatment modes of the YandR system (1410nm, 1927nm and LPTT). Testing was performed safely on the test animals, and the histology results complied with the FDA requirements at 0, 1, 7 and 14 days after treatment. Three [3] female (Yorkshire Cross) crossbred swine were used in this study. During the in-life stage, vital signs were monitored, clinical observations and body weights were monitored and recorded. At the end of the procedure at days 0, 7, and 13, the animal was awakened and transferred to the recovery room. On the last day of trial (day 14), animals were euthanized and skin treatment sites were harvested, sliced and stained with H&E staining. Histopathology analysis showed that by day seven after radiation all treatment sites for all treatment modes were covered with an intact epidermal layer (Re-epithelization). No adverse events or unexpected complications were detected in the swines.

In all instances, the Lumenis YandR Laser System functioned as intended and the results observed were as expected.

Also, similarly to other cleared laser systems with combined wavelengths (K203441) we also histology tested the LPTT mode and found that there were no relevant differences in either the initial shape of the incursion into the skin or in wound healing. Similarly, the histology results showed no overlapping lesions were noted in LPTT treated sites and there was always normal skin tissue between two lesions when present.

VIII. Clinical Data [21 CFR 807.92(b) (2)]

Based on the similarities in the safety and effectiveness profiles of the subject and the predicate, no human clinical studies were deemed needed to support this submission.

IX. Conclusions Safety and Effectiveness SE [21 CFR 807.92(b) (3)]

The Lumenis Y&R Laser System is as safe and effective as the predicate devices. The proposed Lumenis Y&R Laser System has the same intended use and indications, similar technological characteristics, and the same principles of operation as its predicate devices. Thus, the Lumenis Y&R Laser System is substantially equivalent to its predicate.