February 26, 2021

Lumenis Ltd.
℅ Ms. Shlomit Segman
Senior Manager Regulatory Affairs
Lumenis Ltd.
6 Hakidma Street PO Box 240
Yokneam, 2069204
Israel

Re: DEN200028
Trade/Device Name: Lumenis Stellar M22
Regulation Number: 21 CFR 886.5201
Regulation Name: Intense pulsed light device for managing dry eye
Regulatory Class: Class II
Product Code: QIU
Dated: April 17, 2020
Received: April 20, 2020

Dear Ms. Segman:

This letter corrects our previous classification order, dated February 23, 2021, to correct the product code.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Lumenis Stellar M22, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> Universal IPL with a spectrum of 400-1200nm (with different filters) is indicated for: Improvement of signs of Dry Eye Disease (DED) due to Meibomian Gland Dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye, in patients 22 years of age and older with moderate to severe signs and symptoms of DED due to MGD and with Fitzpatrick skin types I-IV. IPL is to be applied only to skin on the malar region of the face, from tragus to tragus including the nose (eyes should be fully covered by protective eyewear). IPL is intended to be applied as an adjunct to other modalities, such as meibomian gland expression, artificial tear lubricants and warm compresses.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Lumenis Stellar M22, and substantially equivalent devices of this generic type, into Class II under the generic name Device for the application of indirect heat for managing dry eye. FDA identifies this generic type of device as:

> **Intense pulsed light (IPL) device for managing dry eye**. An intense pulsed light device for managing dry eye is a prescription device intended for use in the application of intense pulsed light therapy to the skin. The device is used in patients with dry eye disease due to meibomian gland dysfunction, also known as evaporative dry eye or lipid deficiency dry eye.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On April 20, 2020, FDA received your De Novo requesting classification of the Lumenis Stellar M22. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Lumenis Stellar M22 into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request and provided additional information, FDA has determined that, for the previously stated indications for use, the Lumenis Stellar M22 can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks to Health	**Mitigation Measures**
Tissue damage due to overheating	Thermal safety assessment Software verification, validation, and hazard analysis Labeling
Tissue damage or loss of vision due to light radiation	Clinical performance testing Labeling
Adverse tissue reaction	Biocompatibility evaluation
Electrical shock or burn	Thermal safety assessment Electrical safety testing Software verification, validation, and hazard analysis Labeling
Interference with other devices	Electromagnetic compatibility (EMC) testing Software verification, validation, and hazard analysis Labeling
Pain or discomfort	Clinical performance testing Labeling
Failure to mitigate dry eye signs and/or symptoms	Clinical performance testing Labeling

In combination with the general controls of the FD&C Act, the intense pulsed light device for managing dry eye is subject to the following special controls:

(1) Clinical performance testing must evaluate adverse events and improvement of dry eye signs and symptoms under anticipated conditions of use.

(2) Thermal safety assessment in a worst-case scenario must be performed to validate temperature safeguards.

(3) Performance testing must demonstrate electrical safety and electromagnetic compatibility (EMC) of the device in the intended use environment.

(4) Software verification, validation, and hazard analysis must be performed.

(5) The patient-contacting components of the device must be demonstrated to be biocompatible.

(6) Physician and patient labeling must include:

(i) Device technical parameters;
(ii) A summary of the clinical performance testing conducted with the device;
(iii) A description of the intended treatment area location
(iv) Warnings and instructions regarding the use of safety-protective eyewear for patient and device operator;
(v) A description of intense pulse light (IPL) radiation hazards and protection for patient and operator;
(vi) Instructions for use, including an explanation of all user interface components; and
(vii) Instructions on how to clean and maintain the device and its components.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the intense pulsed light device for managing dry eye they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the FD&C 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Morris Kaplan at 301-796-6365.

Sincerely,

Denise L. Hampton -S

for Malvina Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health