June 14, 2023

Lumenis Be, Ltd.
Shlomit Segman
Senior Director RA
6 Hakidma Street PO BOX 240
Yokneam, Yokneam 2069204
Israel

Re: K222790
Trade/Device Name: F65 Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: GEX, ONF, ONG
Dated: May, 2023
Received: May 5, 2023

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,

Jianting Wang -S

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222790

Device Name
F65 Laser System

Indications for Use *(Describe)*
The subject F65 has connection capability with the following available treatment handpieces, for multi-application treatment options. All handpieces are designed for aesthetic and dermatological skin procedure applications, as follows:

The Intense Pulsed Light (IPL) handpiece with a spectrum of 400-1200 nm (with 9 different filters) is indicated for:

- o Benign epidermal lesions, including dyschromia, hyperpigmentation, melasma, and ephelides (freckles)
- o Cutaneous lesions, including warts, scars and striae
- o Benign cutaneous vascular lesions, including port wine stains, hemoangiomas, facial, truncal and leg telangiectasias, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations
- o Removal of unwanted hair and to effect stable long term, or permanent* hair reduction in skin types I-V through selective targeting of melanin in hair follicles
- o Mild to moderate inflammatory Acne (Acne vulgaris)

The Nd:YAG Laser handpiece with a wavelength of 1064 nm (Multi-Spot Nd:YAG) is indicated for:

- o The coagulation and hemostasis of vascular lesions and soft tissue, including the treatment and clearance of superficial and deep telangiectasias (venulectasias) and reticular veins (0.1-4.0 mm. diameter) of the leg
- o The removal of unwanted hair and to effect table long term, or permanent* hair reduction in skin types I-V through selective targeting of melanin in hair follicles
- o The non-ablative treatment of facial wrinkles

The F65 module and handpiece, with wavelength of 1565 nm, are indicated for:

- o Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue
- o Improving the appearance of scalp hair in adult males and females with Fitzpatrick skin type I to IV who are seeking treatment for hair loss.

The Q-Switched Nd:YAG Laser Handpiece with a wavelength of 1064 nm is indicated for:

- o Removal of dark tattoos
- o Treatment of pigmented lesions

*Note
Permanent hair reduction is defined as long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after completion of treatment regime.

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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LUMENIS

5. 510(K) SUMMARY K222790-S001

F65 Laser System and Accessories

Applicant Name:	Lumenis Be Ltd. 9 Hakidma Street PO Box 426 Yokneam Industrial Park, Yokneam 2069236, Israel Tel: +972-77-9599000
Contact Person:	Shlomit Segman, Lumenis Be Ltd. 9 Hakidma Street PO Box 426 Yokneam Industrial Park, Yokneam 2069236, Israel Tel: +972-77-9599230 Email:Shlomit.Segman@lumenis.com
Date Prepared:	June, 2023
Trade Name:	F65 Laser System and Accessories
Common Name:	Powered Laser Surgical Instrument With Microbeam\Fractional Output
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Product Code:	GEX, ONF, ONG
Device Class:	Class II
Regulation Number:	21 CFR 878.4810
Panel:	General & Plastic Surgery
Predicate Devices:	K193500 (Lumenis Stellar M22) Reference: K173846 DermaScalp Laser Cap

Intended Use/ Indications for Use:

The subject F65 Laser System has connection capability with the following available treatment handpieces, for multi-application treatment options. All handpieces are designed for aesthetic and dermatological skin procedure applications, as follows:

The Intense Pulsed Light (IPL) handpiece with a spectrum of 400-1200 nm (with 9 different filters) is indicated for:

- o Benign epidermal lesions, including dyschromia, hyperpigmentation, melasma, and ephelides (freckles)
- o Cutaneous lesions, including warts, scars and striae
- o Benign cutaneous vascular lesions, including port wine stains, hemoangiomas, facial, truncal and leg telangiectasias, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations
- o Removal of unwanted hair and to effect stable long term, or permanent* hair reduction in skin types I-V through selective targeting of melanin in hair follicles
- o Mild to moderate inflammatory Acne (Acne vulgaris)

The Nd:YAG Laser handpiece with a wavelength of 1064 nm (Multi-Spot Nd:YAG) is indicated for:

- o The coagulation and hemostasis of vascular lesions and soft tissue, including the treatment and clearance of superficial and deep telangiectasias (venulectasias) and reticular veins (0.1-4.0 mm. diameter) of the leg
- o The removal of unwanted hair and to effect table long term, or permanent* hair reduction in skin types I-V through selective targeting of melanin in hair follicles
- o The non-ablative treatment of facial wrinkles

The F65 module and handpiece, with wavelength of 1565 nm, are indicated for:

- o Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue
- o Improving the appearance of scalp hair in adult males and females with Fitzpatrick skin type I to IV who are seeking treatment for hair loss.

The Q-Switched Nd:YAG Laser Handpiece with a wavelength of 1064 nm is indicated for:

- o Removal of dark tattoos
- o Treatment of pigmented lesions

*Note
Permanent hair reduction is defined as long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after completion of treatment regime.

Device Description

The Lumenis Be F65 Laser System is intended to be used for the new indication for Improving the appearance of scalp hair in adult males and females with Fitzpatrick skin type I to IV seeking treatment for hair loss, as well as, for the identical set of functions as the predicate device. The description here is limited to the system module required to support the new indication which is the subject of this 510(k):

- The laser console includes a power supply unit, a Laser module (+ aiming beam), a control unit and a PC module. The laser beam is transferred to the handpiece via fiber optics.
- The handpiece includes a scanner module – built of two mirrors that are controlled by two motors directing the Laser beam to desired target tissue.
- The handpiece uses a tip (user may choose from two types) to align the Laser beam focus with the target tissue, enabling a treatment shape size and a tip thermo-electric cooler (TEC).

The F65 is intended for professional use only.

Substantial Equivalence Discussion

The key difference between the Lumenis Be F65 Laser System and its predicate is the new indication for improving the appearance of scalp hair in adult males and females with Fitzpatrick skin type I to IV seeking treatment for hair loss, which has led to this 510(k). While the F65 Laser System delivers the same light wavelength as the predicate, the intensity and pattern of the delivered light to the scalp are specific to the proposed new indication.

Promoting hair growth through exposure to light is not a new concept, as demonstrated by the clearance of the reference device and other devices under the same classification as the reference device.

Safety questions associated with electrical, electromagnetic compatibility, and biocompatibility, are addressed through testing conducted on the predicate device. Animal testing of the subject device's operating parameters addresses both safety and effectiveness questions for the new proposed indication. Likewise, the safety and effectiveness of the device for the proposed indication were also evaluated through two clinical studies of patients seeking treatment for hair loss.

Table 1 provides a comparison, relevant to the F65 module with the 1565 nm laser, which is related to the new proposed indication, of the technical characteristics of the subject device to its predicate and reference devices.

Parameter	Subject Device F65 Laser module System	Predicate Device Stellar M22 1565 nm module (K193500)	Reference Device DermaScalp Laser Cap (K172846)
Regulation Procode Rx/OTC	21 CFR 878.4810 GEX, ONF, ONG Rx	21 CFR 878.4810 GEX, ONF, ONG Rx	21 CFR 890.5500 OAP OTC
Indications for Use	The F65 module and handpiece, with wavelength of 1565 nm, are indicated for: • Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue • Improving the appearance of scalp hair in adult males and females with Fitzpatrick skin type I to IV who are seeking treatment for hair loss.	The 1565 nm Stellar M22 Module & Handpiece, with wavelength of 1565 nm is indicated for use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue.	The family of DermaScalp Laser Cap devices are indicated to treat Androgenetic Alopecia and promote hair growth in Males who have Norwood Hamilton Classifications of IIa to V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in Females who have Ludwig (Savin) Scale I-1 to I-4, II-1, II-2, or frontal; both with Fitzpatrick Skin Types I to IV.
Device Configuration	System console and handpiece	System console and handpiece	Power supply and laser diode caps
Wavelength	1565 nm	1565 nm	650 nm

Type of Laser	Er:Glass Fiber-laser with scanner up to 500 micro-beams per cm^2	Er:Glass Fiber-laser with scanner up to 500 micro-beams per cm^2	Diode lasers at count of - 50, 80, 120, 148, 180, 202, 224, 272
Energy	Up to 70 mJ per microbeam	Up to 70 mJ per microbeam	Total Laser Energy: <5 mW 50 diode lasers: <250mW, 80: <400mW, 120: <600mW, 148: <740mW, 180: <900mW, 202: <1,010mW, 224: <1,120mW, 272: <1,360mW Fluence: ~ 6 J/cm^2
Clinic/Home Use	Clinic Use by professional operator	Clinic Use by professional operator	Home Use

Summary of Clinical Testing and Animal Testing

A preclinical study was conducted to evaluate the Lumenis F65 subject module for hair follicle regeneration capabilities using both Low Level Laser Therapy (LLLT) and untreated controls. The results showed complete tissue repair and formation of hair follicles.

Two clinical studies were conducted to demonstrate that the subject device is safe and effective in patients seeking treatment for hair loss, as indicated. Subjects received multiple treatments over several months, per the protocol described in the Operator's Manual.

In a prospective, single arm study, 32 subjects with hair loss were enrolled, 25 of which completed the entire course of the study. Patients were diagnosed with Androgenic Alopecia (18) or other diagnosis (7) and were evaluated separately. In the Androgenic Alopecia group, the mean age was 32.1 ± 6.4 years. Most of the subjects were female (13/18) and all subjects included were of Fitzpatrick skin type II. For male subjects with androgenic alopecia (n=5) there was an increase of 70.8 ± 35.5 hairs per cm^2 between baseline and the 3-month follow-up visit. For female subjects with androgenic alopecia (n=18) there was an increase of 45.2 ± 30.2 hairs per cm^2 between baseline and 3-month follow-up visit. Pain and discomfort during treatment were assessed with a visual analog scale (VAS) and ranged between 1.97 to 2.33 on a scale from 0 to 10. Post treatment subjects had a trace to mild erythema. No adverse events were reported during the study treatment or follow-up period.

In a second retrospective single arm study, a total of 98 subjects were evaluated for performance, with ages ranging from 21 to 66 years and a mean age of 37.2 ± 9.9 years. Of them, in 44 (44/98, 44.9%) of the cases the documented diagnosis was Androgenic Alopecia, and in 54 cases (54/98, 55.1%) there was no documented diagnosis. Females slightly outnumbered males (51 vs. 47), and the majority of subjects had Fitzpatrick skin type III (60/98, 61.2%), with some having skin types II (18/98, 18.4%) or IV (1/98, 1%). All patient records were reviewed for any reports of adverse events during treatment or follow-up period – no adverse events were reported or documented in patient files. For the 44 subjects with a confirmed diagnosis of androgenic alopecia, the assessment of improvement in scalp hair appearance yielded a correct identification in 97.7% (95% CI: 87.8% -99.7%) of the cases by a group of 3 blinded reviewers. Demonstrating improvement in scalp hair appearance in more than 85% of the patients treated which supports the primary efficacy endpoint of demonstrating improvement in more than 70% of subjects. For the 98 subjects included in the performance analysis, the assessment of improvement in scalp hair appearance yielded a correct identification in 96.9% (95% CI: 91.38 -98.5%) of the cases by a group of 3 blinded reviewers.

Summary of Testing

No new bench testing was required because the testing of the Lumenis predicate devices also applies to the subject device.

Conclusion

The proposed new indication for the subject device does not raise different questions of safety or effectiveness and is adequately supported by the validation testing. The conclusions drawn from the animal and clinical testing, and previously conducted testing of the predicate device, demonstrate that the subject device is as safe, as effective, and performs as well as the predicate.

Thus, the subject device is substantially equivalent to its predicate.