September 9, 2024

Lumenis Be Ltd.
Shlomit Segman
AVP, RA-QA Product Life Cycle (PLC)
9 Hakidma Street PO Box 426, Yokneam Industrial Park
Yokneam, 2069236
Israel

Re: K242349
Trade/Device Name: FoLix
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: August 5, 2024
Received: August 8, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2024.09.09 19:12:25 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical & Infection Control Devices,
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242349

Device Name
FoLix

Indications for Use *(Describe)*
The FoLix System, with wavelength of 1565 nm, is indicated for 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY K242349

FoLix System

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:	August 05, 2024
Trade Name:	FoLix
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Product Code:	GEX, ONG
Device Class:	Class II
Regulation Number:	21 CFR 878.4810
Panel:	General & Plastic Surgery
Predicate Devices:	K222790 (F65 Laser System)

Intended Use/ Indications for Use:

The FoLix System, with wavelength of 1565 nm, is indicated for 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.

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Device Description

The FoLix™ is a laser system intended to be used 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 FoLix™ laser system with a wavelength of 1565 nm and consists of the following:

- 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 to align the Laser beam focus with the target tissue, enabling a treatment shape size and a thermo-electric cooler (TEC).

The FoLix™ is intended for professional use only.

Substantial Equivalence Discussion

The FoLix system is a modification to the previously cleared F65 Laser system (predicate device, K222790). The modification involves the removal of three handpieces (IPL, ND: YAG, and Q-Switch) that were previously supported by the F65 device, leaving the system with a single 1565nm laser handpiece. In addition, minor hardware and software modifications were introduced to support the single applicator, single application configuration. The modified system is substantially equivalent to the previously cleared F65 Laser system.

The Table below provides a comparison of the subject device to its predicate (which will be relevant to the F65 module with the 1565 nm laser).

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Parameter	Predicate device F65 Laser module System (K222790)	Subject device FoLix
Product Code	GEX, ONF, ONG	GEX, ONG
Regulation	21 CFR 878.4810	21 CFR 878.4810
Rx/OTC	Rx	Rx
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 FoLix Laser System, with wavelength of 1565 nm, is indicated for 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.
Device Configuration	System console and handpiece	System console and handpiece
Wavelength	1565 nm	1565 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
Energy	Up to 70 mJ per microbeam	Up to 70 mJ per microbeam
Clinic/Home Use	Clinic Use by professional operator	Clinic Use by professional operator

Summary of Bench Verification

To support the FoLix System, the following activities were performed:

- Risk analysis per ISO 14971
- Electrical, laser and electromagnetic compatibility safety testing according to IEC 60601-1 and IEC 60601-1-2
- Software verification and validation according to IEC 62304 and FDA Guidance “Principles of Software Validation Guidance for Industry and FDA Staff, January 2002”.
- System testing (e.g., user need, functionality, communication).
- Usability assessment to ensure that the usability of the product was not affected according to FDA Guidance “Applying Human Factors and Usability Engineering to Medical Devices, February 2016”, IEC 62366-1 and IEC 60601-1-6.

Summary of Clinical Validation

No new clinical validation was required to support the FoLix as the clinical validation of the Lumenis predicate device also applies to the subject device.

Conclusion

The subject device does not raise different types of safety or effectiveness questions. The conclusions drawn from these testing, and previously conducted testing of the predicate and legacy devices, demonstrate that the subject device is as safe, as effective, and performed as well as the predicate.

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