June 2, 2026

Lumenis Be, Ltd.
Shlomit Segman
Avp, RA-qa Plc
Hakidma St. 9, P.O.B 426
Yokneam Ilit, 2069236
Israel

Re: K253803
Trade/Device Name: MILAN System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 7, 2026
Received: May 7, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.06.02 17:41:48 -04'00'

Colin Kejing Chen, Ph.D.
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253803

Please provide the device trade name(s).

MILAN System

Please provide your Indications for Use below.

The MILAN System is indicated for use in dermatological procedures for electrocoagulation and hemostasis. At higher energy levels greater than 62 mJ/pin, the use of the Milan System with its disposable tips is limited to Skin Types I-IV.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(K) SUMMARY

MILAN System

510(K) Number K253803

Applicant Name:	Shlomit Segman, Ph.D.
Company & Applicant name:	Lumenis Be Ltd. 9 Hakidma Street PO Box 426 Yokneam Industrial Park, Yokneam 2069236, Israel Tel: +972-77-9599000 Email: Shlomit.Segman@lumenis.com

Date Prepared:	May28, 2026
Trade Name:	MILAN System
Classification Name:	Electrosurgical cutting and coagulation devices and accessories.
Product Code:	GEI
Device Class:	Class II
Regulation Number:	21 CFR 878.4400
Panel:	General & plastic surgery
Predicate Device:	K240999 (Legend X Applicator VO)

Intended Use/ Indications for Use:

The MILAN System is indicated for use in dermatological procedures for electrocoagulation and hemostasis. At higher energy levels greater than 62 mJ/pin, the use of the MILAN System with its disposable tips is limited to Skin Types I-IV.

Device Description:

The MILAN System is a computerized radiofrequency microneedling (RFMN) device. The system consists of a console, a handheld applicator, various disposable tip configurations, and a footswitch. The applicator connects to the console via a dedicated cable, and RF energy is delivered by activating either the footswitch or the trigger button on the applicator. Disposable tips are attached to the applicator and deliver radiofrequency electrical current through an array of micro-electrode pins to the treatment area. The system allows for adjustable needle lengths of up to 4 mm, enabling precise delivery of RF energy through the microneedle array.

Substantial Equivalence Discussion

The Indication for use and technological characteristics of the MILAN System are substantially equivalent to the indication for use and technological characteristics of the FDA cleared Legend X Applicator VO (K240999).

The Table below provides a comparison of the subject device to its predicate device

Parameter	Subject device MILAN System Lumenis Be Ltd.	Predicate Device Legend X Applicator VO Pollogene Ltd. (K240999)	Substantial Equivalence (SE) Analysis
Device classification and Indication for Use			
Product Code and class	GEI, Class II	GEI, Class II	Substantial Equivalence
Regulation	21 CFR 878.4400	21 CFR 878.4400	Substantial Equivalence
Indications for Use	The **MILAN System** is indicated for use in dermatological procedures for electrocoagulation and hemostasis. At higher energy levels greater than 62 mJ/pin, the use of the MILAN System with its disposable tips is limited to Skin Types I-IV.	The **Legend X Applicator VO with the genXL** is indicated for use in dermatological procedures for electrocoagulation and hemostasis. At higher energy levels greater than 62 mJ/pin, the use of the Legend X Applicator VO with its disposable tips (e.g. genXL) is limited to Skin Types I-IV.	Substantial Equivalence
Clinical use	Prescription Use	Prescription Use	Substantial Equivalence
Environment Used	Hospitals or aesthetic clinics, specialized medical clinics, depending on local regulation.	Hospitals or clinics depending on local regulation	Substantial Equivalence

Parameter	Subject device MILAN System Lumenis Be Ltd.	Predicate Device Legend X Applicator VO Pollogene Ltd. (K240999)	Substantial Equivalence (SE) Analysis
Device Technological Characteristic			
Energy used/ Delivery	RF energy	RF energy	Substantial Equivalence
Performance specifications	Input power: 100-240V, 50-60 Hz RF Frequency: 1MHz Maximal RF output power: up to 50W, 50-1000Ω	Input power: 100-240V, 50-60 Hz RF Frequency: 1 MHz Maximal RF output power: up to 50W, 50-1000Ω	Substantial Equivalence Impedance within range of legally cleared device
Tip configuration (number of needles)	Single needle group array: 36 Dual needle group arrays: 25 or 36 or 61	gen12: 12 gen36: 36 gen36L: 36 gen100: 100 H7x7: 49 genXL: 36	Substantial Equivalence Within range of predicate device
Maximum needle length	4mm	4mm (for genXL tip)	Substantial Equivalence
Distance Between Needles	Needle group 5X5: 2.2mm Needle group 6X6: 2.2mm Sequential mode; 5X5 followed by 6X6:1.55mm	gen tips':1.5mm- 2.2mm	Substantial Equivalence Within the predicate's range
Needle Thickness	270µm	270µm	Substantial Equivalence
Patient contacting Materials	Insulated stainless steel	Insulated stainless steel	Substantial Equivalence

Parameter	Subject device MILAN System Lumenis Be Ltd.	Predicate Device Legend X Applicator VO Pollogene Ltd. (K240999)	Substantial Equivalence (SE) Analysis
Needle Insulation	Insulated Parylene C, exposed blunt end	Insulated Parylene C, exposed blunt end	Substantial Equivalence
Biocompatibility	All body contact materials are biocompatible	All body contact materials are biocompatible	Substantial Equivalence
Sterility	Single use, disposable, ETO sterilized.	Single use, disposable, ETO sterilized.	Substantial Equivalence

Non-Clinical (Bench) Performance Data:

The following performance tests were performed to support the MILAN System:

- Electrical safety and electromagnetic compatibility safety according to IEC 60601-1-2, IEC 60601-2-2 and IEC 60601-1 standards.
- 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”, and IEC 62366-1, and IEC 60601-1-6 standards.
- Biocompatibility evaluation according to ISO 10993-1 standard and FDA Guidance “Use of International Standard ISO 10993- 1, “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process, September 2023”.
- Packaging for terminally sterilized per ISO 11607-1 standard.
- Sterilization of health-care products - Ethylene oxide per ISO 11135 standard.
- Software verification and validation according to IEC 62304 standard and the FDA Guidance “Principles of Software Validation Guidance for Industry and FDA Staff, January 2002
- Risk analysis per ISO 14971 standard.
- Bench performance testing was executed according to the FDA Guidance on Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery , March 2020, demonstrating that the RF frequency and output of the MILAN System is as that of the predicate device with slight difference in impedance levels when reaching RF curve peak, which remains consistent with those of legally FDA cleared and marketed device.
- An Ex-vivo, tissue study was performed in accordance with the FDA Guidance on Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery, March 2020 and the FDA Draft Guidance on the Evaluation of Thermal Effects of Medical Devices that Produce Tissue Heating and/or Cooling, March 2024. The ex-vivo study evaluated the device’s thermal effects on porcine abdominal tissue. Both the MILAN

System and the predicate device were operated at three comparable energy levels to assess thermal effect under similar conditions.

In summary, all the above-mentioned performance tests were executed to verify the overall functionality of the subject device, ensuring it operates as specified by the design input requirements. This included testing various functional safety features as well as general operational capabilities. The requirements for safety and effectiveness, including adherence to regulatory standards, were thoroughly verified. Results of verification testing confirm that the subject device conforms to design specifications and requirements and meets the needs of the intended users.

Animal Performance Data/Histological Data:

Not Applicable

Clinical Performance Data:

Not Applicable

Conclusion

The comparison of the MILAN System to its predicate device along with the performance testing conducted on the subject device demonstrates that the MILAN System is as safe and effective and substantially equivalent to its predicate device, the Legend X Applicator VO with its accessories, FDA cleared under 510(k) K240999, and therefore, may be legally marketed in the USA.