May 8, 2024

Pollogen Ltd.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

RE: K240999
Trade/Device Name: Legend X Applicator VO
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 11, 2024
Received: April 11, 2024

Dear Prithul Bom:

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.

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,

Long H. Chen -S Digitally signed by Long H. Chen -S
Date: 2024.05.08 13:39:12 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K240999

DeviceName
Legend X Applicator VO

Indications for Use *(Describe)*
The Legend X Applicator VO and its accessories are intended for dermatological procedures requiring ablation and resurfacing of the skin when using VoluDerm Energy (tips gen12, gen100, gen 36, gen36L, H7x7). The Legend X Applicator VO with genXL tip is intended for use in dermatological procedures for electrocoagulation and hemostasis. At higher energy levels greater than 62 mJ/pin, use of the Applicator VO with genXL tip is limited to Skin Types I-IV.

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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510(k) Summary

K240999

1. General information

510(k) Submitter	Pollogen Ltd 6 Kaufman Street Tel Aviv, IL 6801298
FDA Registration Number	3008753275
Primary Correspondent	Karen Smith Vice President, Regulatory & Quality Lumenis Be, Inc., a Pollogen Ltd Family Company
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Date Prepared	April 11, 2024

2. Device Identification

The **Legend X Applicator VO** consists of an applicator and applicator accessories (disposable tips) needed to perform some of Legend X dermatological procedures. The **Legend X Applicator VO** can be defined as follows:

Proprietary Name	***Legend X Applicator VO***
Device Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Description:	Electrosurgical Cutting and Coagulation Device and Accessories
Regulation Number:	878.4400
Device Class:	Class II
Product Code:	GEI

3. Predicate Devices

Primary Predicate:

Proprietary Name	***Legend X Platform***
Device Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Description:	Electrosurgical Cutting and Coagulation Device and Accessories
510(k) Number:	K232903
Regulation Number:	878.4400

Device Class:	Class II
Product Code:	GEI, NGX

Secondary Predicate:

Proprietary Name	***InMode System with the Morpheus8 Applicators***
Device Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Description:	Electrosurgical Cutting and Coagulation Device and Accessories
510(k) Number:	K200947
Regulation Number:	878.4400
Device Class:	Class II
Product Code:	GEI

4. Device Description

The **Legend X Applicator VO** ("Proposed Device") is connected to the Legend X software-controlled capital equipment platform to enable application of radiofrequency onto the skin for ablation and resurfacing or electrocoagulation and hemostasis. The proposed device applicator and applicator accessories are identical to the recently cleared Legend X Platform (K232903), with the exception of the new optional Applicator VO genXL disposable tip. The application of radiofrequency with the Applicator VO Disposable Tip only occurs under the continuous and direct control of a user with direct visualization, via the user inputs into the Legend X Console and Applicator indicators.

The proposed device consists of applicators and applicator accessories (disposable tips) needed to perform some of Legend X dermatological procedures. The summary descriptions of the proposed device are outlined below.

Legend X Applicator VO: The Legend X Applicator VO is a handheld handpiece which delivers energy to the treatment area. Depending on the selected user inputs, the user can utilize the applicator to deliver fractional RF energy for ablation and resurfacing, or electrocoagulation and hemostasis, as a means for noninvasive skin treatment throughout the face and body. The Applicator VO is connected to the cleared Legend X Console via an Applicator Connector cord.

Legend X Software: The Legend X Software provides the user and patient with the ability to safely commence, drive, and stop the operation of the Applicator on the skin area of interest throughout the face and body. It receives user input from the Legend X Console and computes the appropriate output to the Applicator VO connected to the Console. It provides a graphical user interface where the treatment parameters are adjusted as well as status of operation is shown in real time and displays important system status information.

Legend X Applicator VO Disposable Tips: The Legend X Applicator VO Disposable Tips set is part of the Legend X Applicator VO kit. The Legend X Applicator VO Disposable Tips Set includes:

1. gen12 disposable tip
2. gen36 disposable tip
3. gen36L disposable tip
4. gen100 disposable tip
5. H7X7 disposable tip
6. genXL disposable tip

The patient-contacting portions of the disposable tips are constructed of stainless steel and gold plating. The disposable tips are connected to handheld Applicator VO for delivery of radiofrequency electrical current via an array of micro-electrode pins onto the skin surface.

5. Intended Use/Indications for Use

The **Legend X Applicator VO** and its accessories are intended for dermatological procedures requiring ablation and resurfacing of the skin when using VoluDerm Energy (tips gen12, gen100, gen 36, gen36L, H7x7). The Legend X Applicator VO with genXL tip is intended for use in dermatological procedures for electrocoagulation and hemostasis. At higher energy levels greater than 62 mJ/pin, use of the Applicator VO with genXL tip is limited to Skin Types I-IV.

6. Comparison of Technological Characteristics with the Predicate Devices

Overall, the proposed and predicate devices are based on the following similar basic technological elements:

1. Device contains a central console that connects each of the main components to facilitate dermatologic procedures and facilitates the selection of fractional RF treatment modes via the graphic user interface
2. Device contains an applicator to allow energy delivery and application on to the area of interest on the skin
3. Device contains similar components between the subject and predicate devices (i.e., Applicator VO and disposable tips)
4. Device requires continuous direct control by the user to operate the Applicator
5. Device mode operation is only at the command of the user

Comparison of the technological characteristics with the predicate devices for each of the **Legend X Applicator VO** disposable tip components are described below:

Proposed Device **Legend X Applicator VO**	**Primary Predicate** **Legend X Platform (K232903)**	**Secondary Predicate** **InMode System (K200947)**	**Technological Characteristics Comparison**
Components: - Applicator VO (connected to a cleared Legend X Console) with accessories	System Components: - Console - Patient-controlled manual switch - Applicators (1, 2, 3, and VO) - Footswitch	System Components: - Console - Applicator - Footswitch	**Identical Characteristics:** • The Legend X Applicator VO is identical to the primary predicate Legend X Platform in functionality, design, and specifications. **Differences** • The subject Legend X Applicator VO is compatible with six disposable tip accessories, whereas the primary predicate is compatible with five disposable tip accessories.
Applicator VO Disposable Tips: • gen12 • gen36 • gen36L • gen100 • H7x7 • **genXL**	Applicator VO Disposable Tips: • gen12 • gen36 • gen36L • H7x7 • gen100	Accessories • T tip head • 12-pin tip head • 24-pin tip head • 40-pin tip head	**Identical Characteristics:** • Functionality: To provide delivery of fractional RF energy • Similar materials, specifications, and intended functionality **Differences** • The Applicator VO genXL disposable tip is an additional disposable tip with insertion depth options of up to 4 mm, which is within the range of the secondary predicate's disposable tips that are up to 7 mm.

7. Performance Data

The **Legend X Applicator VO** was assessed for performance in accordance with internal design specification with the applicable performance standards to demonstrate safety and effectiveness.

The testing identified no new issues of safety or effectiveness. The testing performed are summarized below:

Summary of Performance Testing:

The reprocessing, sterilization, and shelf life for the subject device are identical to those evaluated for the primary predicate. The Legend X. Applicator VO disposable tips are EO sterilized for single use, and the Legend X Applicator VO is reusable.

Biocompatibility: The final finished form of the subject device has been used for the biocompatibility evaluation. Biocompatibility for patient-contacting components has been evaluated and validated in accordance with the provisions of the following guidance document and standards:

- *FDA Guidance for Industry and Food and Drug Administration Staff – Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."*
- *ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*
- *ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*
- *ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization*
- *ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity*
- *ISO 10993-23 Biological evaluation of medical devices - Part 23: Tests for irritation*

Electrical Safety and Electromagnetic Compatibility: The subject device has been fully evaluated for electrical safety and EMC compliance and is compliant with IEC 60601-1 standards.

Software: Software was developed, tested, and verified per Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

Results of verification and validation (V&V) testing confirm that the proposed device conforms to design specifications and meets the needs of the intended users.

V&V Testing: Performance testing was executed to verify the overall functionality of the proposed device to operate as specified by the design input requirements, including applicator and controls, various functional safety features, and other general functionality. Requirements

for safety and effectiveness of the device, including the adherence to regulatory standards, were verified. Results of verification testing confirm that the subject device conforms to design specifications and requirements and meets the needs of the intended users.

8. Conclusion

Based on the same Indications for Use and similar technological characteristics as the secondary predicate and performance testing, the **Legend X Applicator VO with genXL tip** raises no new questions of safety and effectiveness and is substantially equivalent to the secondary predicate device in terms of safety, effectiveness, and performance.