November 1, 2024

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

Re: K243217
Trade/Device Name: Legend X Desktop System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, NGX
Dated: October 3, 2024
Received: October 3, 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.

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.11.01 13:53:12 -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)*
K243217

Device Name
Legend X Desktop System

Indications for Use *(Describe)*
The Legend X Desktop System and its accessories are intended for dermatological procedures requiring ablation and resurfacing of the skin when using VoluDerm Energy (Applicator VO).

It is also intended for use in dermatologic and general surgical procedures for non-invasive treatment when using RF Energy and for muscle conditioning to stimulate healthy muscles (TriPollar Applicator).

Legend X Desktop System is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind.

Legend X Desktop System is intended to be operated by a licensed health care practitioner who is present to monitor treatment.

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.**

**510(k) Summary**

**K243217**

## 5.1. General information

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|---|---|
| **510(k) Submitter** | Pollogen Ltd<br>6 Kaufman Street Tel<br>Aviv, IL 6801298 |
| **FDA Registration Number** | 3008753275 |
| **Primary Correspondent** | Karen Smith<br>Vice President, Regulatory & Quality<br>Lumenis Be, Inc., a Pollogen Ltd Family Company |
| **Contact Information** | Email: karen.smith@lumenis.com |
| **Date Prepared** | November 22, 2023 |

## 5.2. Device Identification

The Legend X Desktop System consists of a Desktop console with connected components including: applicators and applicator accessories (disposable tips) needed to perform some of Legend X Desktop dermatologic procedures. The Legend X Desktop System can be defined as follows:

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|---|---|
| **Proprietary Name** | Legend X Desktop System |
| **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, NGX |

## 5.3 Predicate Device

| | |
|---|---|
| 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 |

**Reference Device**

| | |
|---|---|
| Proprietary Name | Veinoplus Sport Neuromuscular Stimulator |
| Device Classification Name: | Stimulator, Muscle, Powered, For Muscle Conditioning |
| Regulation Description: | Powered muscle stimulator |
| 510(k) Number: | K141919 |
| Regulation Number: | 890.5850 |
| Device Class: | Class II |
| Product Code: | NGX, GXY |

### 5.4. Device Description

The Legend X Desktop System ("Proposed Device") is a software-controlled capital equipment system that enables application of radiofrequency energy onto the skin for ablation, resurfacing, or noninvasive treatment or muscle activation pulses. The application of radiofrequency energy or muscle activation pulses only occurs under the continuous and direct control of a user with direct visualization, via the user inputs into the console, applicator indicators and subsequent operation.

The proposed device consists of a console with connected applicators, and applicator accessories (disposable tips) needed to perform some of Legend X Desktop dermatological and general surgical procedures. The summary descriptions of each component are outlined below.

Legend X Desktop Console: The Legend X Desktop Console (also known as the Console or Main Control Unit) contains the graphic display interface for the user that is provided by a touchscreen monitor for viewing and a computer running the Legend X Desktop software. The monitor allows for user input during initial setup and throughout the session. The console also provides power and connectivity for the applicators.

Legend X Desktop Applicators: The Legend X Desktop Applicators (TriPollar and VO) are handheld handpieces which deliver energy to the treatments area. Depending on the applicator and selected user inputs, the user can utilize the applicators to deliver either muscle energy onto the muscles of the face and body or RF energy for ablation and resurfacing or noninvasive treatment onto the skin. Each applicator is connected to the console via an applicator connector cord.

Legend X Desktop Software: The Legend X Desktop software provides the user and patient with the ability to safely commence, drive, and stop the operation of the applicators on the skin or muscle area of interest throughout the face and body. It receives user input from the subject console to compute the appropriate output via the chosen applicator connected to the console. It provides a graphical user interface where the treatment timeline as well as status of operation is shown in real time and displays important system status information.

Legend X Desktop Disposable Tip Accessories: The Legend X Desktop disposable tips set

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

- gen12 disposable tip,
- gen36 disposable tip,
- gen36L disposable tip,
- gen100 disposable tip, and
- H7X7 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 RF energy via an array of multi-electrode pins onto the skin surface.

### 5.5. Intended Use/Indications for Use

The Legend X Desktop System and its accessories are intended for dermatological procedures requiring ablation and resurfacing of the skin when using VoluDerm Energy (Applicator VO).

It is also intended for use in dermatologic and general surgical procedures for non-invasive treatment when using RF Energy and for muscle conditioning to stimulate healthy muscles (TriPollar Applicator).

Legend X Desktop System is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind.

Legend X Desktop System is intended to be operated by a licensed health care practitioner who is present to monitor treatment.

### 5.6. Comparison of Technological Characteristics with the Predicate Device

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

- Device contains a central console that connects each of the main components to facilitate dermatologic and general surgical procedures and facilitates the selection of either RF energy or muscle stimulation (pulses) via the graphical user interface
- Device contains applicators to allow energy delivery and application of the selected mode on to the treatment area
- Device contains similar components between the subject and predicate devices (i.e., desktop console, applicators, and disposable tips)
- Device requires continuous direct control by the user to operate the Applicators
- Device mode operation is only at the command of the user
- Device mode operation may be halted at the command of the user

The primary differences between the predicate and the Legend X Desktop System is the smaller desktop console as well as differences in applicator options. In addition to providing equivalent means of ablation and resurfacing of the skin via the applicators and applicator accessories, the Legend X Desktop System includes identical compatible accessories for the VO applicator to facilitate dermatological

procedures, gen12, gen36, gen36L, gen100, and H7x7. The Legend X Desktop System is a different configuration of Applicator VO with 5 disposable tips and the tripollar Applicator. For this reason, additional testing for the entire system was performed and is captured as part of this submission. Comparison of the technological characteristics with the Predicate Device for each of the Legend X Desktop System components are described below:

| **Comparison Criteria** | **Proposed Device** **Legend X Desktop System (K243217)** | **Predicate Device** **Legend X Platform (K232903)** | **Comparison Assessment** |
|---|---|---|---|
| **Fundamental Scientific Technology** | Software-Based system that provides radiofrequency electrical current or pulsed muscle conditioning to stimulate healthy muscles via the electrodes of the applicators and accessories. Operation is under the continuous and direct control of the healthcare professional. | Software-Based system that provides radiofrequency electrical current and or pulsed muscle conditioning to stimulate healthy muscles via the electrodes of the applicators and accessories. Operation is under the continuous and direct control of the healthcare professional. | Same |
| **Primary Mode of Action** | User input to start or stop application of radiofrequency or transcutaneous electrical muscle stimulation through electrodes of applicators and accessories | User input to start or stop application of radiofrequency or transcutaneous electrical muscle stimulation through electrodes of applicators and accessories | Same |
| **Major Components** | Consists of 3 Major Components and an optional accessory<br>• Legend X Desktop Console with external power supply<br>• 2 Legend X Desktop Applicators | Consists of 4 Major Components and an optional accessory<br>• Legend X Console<br>• 4 Legend X Applicators<br>• Legend X Foot Switch<br>• Legend X Patient Manual Controlled Switch | Similar, predicate contains additional major components and larger capital equipment |

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|---|---|---|---|
| **Accessories** | 6 Disposable tips:<br>• gen12,<br>• gen36,<br>• gen 36L,<br>• gen100,<br>• H7x7 | 6 Disposable tips:<br>• gen12,<br>• gen36,<br>• gen 36L,<br>• gen100,<br>• H7x7 | Same as predicate |
| **Control / User Interface** | • Connected handheld applicators designed to apply RF energy or pulses (Applicators Tripollar and VO)<br>• USB interface for software updates | • Connected handheld applicators designed to apply RF energy or pulses (Applicators 1, 2, 3, and VO)<br>• Connected handheld patient manual switch designed to stop operation<br>• Connected foot switch designed to start / continue operation<br>• USB interface for software updates | Similar to predicate, subject controls and user interface are within range of the predicate. |
| **System Weight** | ~5 Kgs/11lbs | ~30 Kgs/66.14lbs | Legend X Desktop includes a miniature console that is lighter in weight than the larger Legend X platform predicate. However, the miniature console does not introduce any new questions of safety or effectiveness as the technological specifications are similar to the predicate console. |
| **System Dimensions hxwxd** | 32cm x 32cm x 43cm<br>12.6” x 22.6” x 17” | 110cm x 45cm x 45cm<br>43.3” x 17.72” x 17.72” | Legend X Desktop includes a miniature console that is smaller in size than the larger cleared Legend X platform predicate console. |

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|---|---|---|---|
| **Mode Application** | Stainless steel electrodes /disposable tips connected to system applicator emit energy/pulses to the skin while user moves applicator across treatment area | Stainless steel electrodes /disposable tips connected to system applicator emit RF energy/pulses to the skin while user moves applicator across treatment area | Same |
| **No. of Applicators and Applicator Type** | 2 Applicators<br>• Applicator VO<br>• Applicator Tripollar | 4 Applicators<br>• Applicator VO<br>• Applicator 1<br>• Applicator 2<br>• Applicator 3 | Similar, subject includes two applicators (Applicators VO and Tripollar), whereas predicate includes 4 applicators (Applicators VO an 1-3). However features of subject applicators are within range of the predicate and legally marketed devices. |
| **Number and type of Disposable Tips** | 5 Disposable Tips:<br>• gen12,<br>• gen36,<br>• gen36L,<br>• gen 100, and<br>• H7x7 | 5 Disposable Tips:<br>• gen12,<br>• gen36,<br>• gen36L,<br>• gen 100, and<br>• H7x7 | Same as predicate |
| **RF energy per pin** | up to 62mJ/pin | up to 62mJ/pin | Same as predicate |
| **Maximum number of pulses per tip** | 800 | 800 | Same as predicate |
| **Modes of Operation (treatment programs)** | Low, Medium, High | Low, Medium, High | Same as predicate |
| **Biocompatibility** | All parts that are in contact with patient comply with requirements of ISO 10993-1 and FDA guidance | All parts that are in contact with patient comply with requirements of ISO 10993-1 and FDA guidance | Same as predicate |

| | | | |
|---|---|---|---|
| **Software** | Verified and validated according to the FDA guidance | Verified and validated according to the FDA guidance | Same as predicate |

### 5.4. Performance Data

The Legend X Desktop System 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:

- *Cleaning and Sterilization: The cleaning and disinfection instructions provided in labeling for non- disposable components were validated as per AAMI TIR-30. Single-use disposable sterile (EO) devices and EO residual were validated in accordance with ISO 11135* and *ISO10993-7. The shelf life and sterile barrier packaging of the single-use disposable devices were evaluated per ASTM F1980-16, ASTM F 1929-15, ASTM F88/F88M-15, and ISO 11607.*

- *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 provision of the following FDA Guidance document, "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" and applicable ISO 10993 standards.*

- *Electrical Safety, Performance and EMC: The subject device has been fully evaluated for electrical safety and EMC compliance to IEC 60601 series standards.*

- *Software: Software was developed, tested, and verified per the FDA guidance document: Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices and results of verification and validation 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 efficacy of the system, including but not limited to the adherence to regulatory standards were verified. Results of verification testing confirm that the proposed device conforms to design specifications and requirements and meets the needs of the intended user.*

- *Animal Testing: Performance testing - animal testing was executed according to General Considerations for Animal Studies Intended to Evaluate Medical Devices issued on March 28, 2023.*

### 5.8 Conclusion

Based on the indication for use, technological characteristic, performance testing and comparison to the predicate devices, the Legend X Desktop System raises no new questions of safety and effectiveness as compared to the predicate and reference devices and is substantially equivalent to the predicate in terms of safety, efficacy, and performance for the requested indications for use.