



September 12, 2025

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

Re: K252576
Trade/Device Name: Legend X Platform
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, NGX, NFO
Dated: August 14, 2025
Received: August 14, 2025

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,

Tushar Bansal -S

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K252576

Device Name

Legend X Platform

Indications for Use (Describe)

The Legend X Platform 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 the non-invasive treatment of mild to moderate facial wrinkles and rhytides when using TriPollar radiofrequency (RF) Energy and for transcutaneous electrical stimulation of periorbital, facial, and body muscles with DMSt (Dynamic Muscle Stimulation technology) for aesthetic purposes, including improvement of appearance, and for body muscle conditioning to stimulate healthy muscles. (Applicators 1-3).

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.

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510(k) Summary**K252576****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
Contact Information	Email: karen.smith@lumenis.com
Date Prepared	September 11, 2025

2. Device Identification

The **Legend X Platform** consists of a Console with connected components including: a Foot Switch, Patient Controlled Manual Switch, Applicators, and Applicator accessories (disposable tips) needed to perform some of Legend X dermatologic procedures. The **Legend X Platform** can be defined as follows:

Proprietary Name	<i>Legend X Platform</i>
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, NFO

3. Predicate Device(s)

Predicate:

Proprietary Name	<i>Legend X Platform</i>
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

4. Device Description

The **Legend X Platform** (“Proposed Device”) is a software-controlled capital equipment platform that enables application of radiofrequency (RF) energy onto the skin for ablation, resurfacing, or noninvasive treatment of wrinkles and rhytides or electrical stimulation of skin and muscles throughout the face and body. The application of RF or dynamic muscle stimulation 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 of the Foot Switch and Applicators.

The proposed device consists of a Console with connected Foot Switch, Patient Controlled Manual Switch, Applicators, and Applicator accessories (disposable tips) needed to perform some of Legend X dermatological and general surgical procedures. The summary descriptions of each component are outlined below.

Legend X Console: The Legend X 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 software. The monitor allows for user input during initial setup and throughout the session. The console also provides power and connectivity for the applicators, foot switch, and patient manual-controlled switch.

Legend X Foot Switch: The Legend X Foot Switch (Foot Switch) is connected to the Legend X Console via a connector cord. The Foot Switch enables or disables the energy delivery through the applicators to treatment area.

Legend X Applicators: The Legend X Applicators (1, 2, 3 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 of wrinkles and rhytides onto the skin throughout the face and body. Each applicator is connected to the Console via an Applicator Connector cord.

Legend X Patient Controlled Manual Switch: The Legend X Patient Controlled Manual Switch is also a handheld device that serves as the patient interface that allows the patient to stop the operation of the chosen treatment mode upon the press of a button. In this situation, the system does not allow operation to continue. A Patient Controlled Manual Switch cord connects the Patient Controlled Manual Switch to the Console. 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 Applicators on the skin or muscle area of interest throughout the face and body. It receives user input from the Legend X Console, Foot Switch, and Patient Manual Controlled Switch, and computes the appropriate output to 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 Disposable Tips: The Legend X Disposable Tips set is part of the Legend X Platform accessories kit. The Disposable Tips Set includes:

- gen12 disposable tip
- gen 36 disposable tip
- gen 36L disposable tip
- gen 100 disposable tip
- 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 radiofrequency electrical current via an array of multi-electrode pins onto the skin surface.

5. Intended Use/Indications for Use

The Legend X Platform 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 the non-invasive treatment of mild to moderate facial wrinkles and rhytides when using TriPollar radiofrequency (RF) Energy and for transcutaneous electrical stimulation of periorbital, facial, and body muscles with DMSt (Dynamic Muscle Stimulation technology) for aesthetic purposes, including improvement of appearance, and for body muscle conditioning to stimulate healthy muscles. (Applicators 1-3).

6. Comparison of Technological Characteristics with the Predicate Devices

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, muscle stimulation, or fractional RF treatment modes via the graphic user interface
- Device contains applicators to allow energy delivery and application of the selected mode on to the area of interest on the skin or muscles throughout the face and body
- Device contains similar components between the subject and predicate devices (i.e., console, foot switch, applicators, patient manual-controlled switch, 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 either the user or the patient

The main difference between the proposed device and the predicate, Pollogen's Legend X Platform (K232903), is that the Legend X Platform includes two slightly modified applicators (Applicators 1-2) with an integrated secondary temperature indicator and slightly modified specifications. Furthermore, the indications have been updated to clarify the intended purpose of the device. The Legend X Platform is an upgraded version of the predicate device. For this reason, additional testing 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 Platform** components are described below:

Proposed Device Legend X Platform	Predicate Pollogen Legend X Platform (K232903)	Technological Characteristics Comparison
System Console/ Main Control Unit	System Console/ Main Control Unit	Identical Characteristics: • <u>Functionality</u>: To provide central connection to all device components; as well as a user interface for user inputs during setup • Similar specifications and materials Differences • Minor updates to power and current density specifications^{1,2} • Minor updates to graphical user interface (GUI)
Foot Switch	Foot Switch	Same
Patient-controlled manual switch	Patient-controlled manual switch	Same
Applicators (1, 2, 3, and VO)	Applicators (1, 2, 3, and VO)	Identical Characteristics: • Functionality: To provide delivery of DMSt and RF energy • Similar specifications and intended functionality. Differences • Two slightly modified applicators (Applicators 1-2: same materials with additional secondary temperature indicator; no changes to intended functionality or operation)
Disposable Tips: • Gen12 • Gen36 • Gen36L • Gen100 • H7x7	Disposable Tips: • Gen12 • Gen36 • Gen36L • Gen100 • H7x7L	Same

¹Rationale for power density update: The increased maximum power density to 30 mW/cm² remains within range of FDA 1999 FDA Guidance maximum of 0.25 W/cm² and is consistent with legally marketed devices, including K241102 cleared for facial aesthetic stimulation. Accordingly, the device does not raise new questions of safety or effectiveness.

²: Rationale for current density update: The increased maximum current density for Applicator 2 to 4 mA/cm² is

greater than the conservative general safety limit of 2mA/cm² specified by IEC 60601-2-10 but is justified by the risk analysis provided in accordance with this standard, in view of the added temperature indicators for Applicators 1 and 2 as a risk mitigation, plus the acceptably low power density.

Comparison of Technological Differences: The main technological difference between the proposed device and the predicate, Pollogen's Legend X Platform (K232903), is the updated maximum root-mean-squared (rms) power density and that Applicators 1 and 2 now include an integrated secondary temperature sensor. The maximum rms power density of the subject device using smallest electrode conductive surface area @ 500Ω is 0.03 W/cm², which remains well below the FDA guidance limit of 0.25 W/cm² for powered muscle stimulators and is consistent with legally marketed devices cleared for facial aesthetic stimulation, such as K241102. These modifications do not raise new questions of safety or effectiveness. To support this conclusion, additional verification and validation testing was performed on the modified system, as described below.

7. Performance Data

The **Legend X Platform** 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, including testing performed on the original version of the Legend X Platform (K232903, predicate device) as well as updated verification and validation (V&V) testing performed to evaluate the new and modified functions of the updated (subject) device:

Summary of Performance Testing:

Reprocessing, Sterilization, and Shelf Life: identical to the predicate, the Legend X Platform disposable tips are EO sterilized for single use and the Legend X Platform and non-disposable components including the applicators are reusable.

Reprocessing

Cleaning: The cleaning and disinfection instructions provided in labeling for non-disposable components were validated against the following standard:

- *AAMI TIR-30:2011 – A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*

Sterility: Single- use disposable sterile (EO) devices and EO residual were validated in accordance with the following standards:

- *ISO 11135:2014 – Sterilization of healthcare products – Ethylene Oxide – Requirements for development validation and routine control of a sterilization process for medical devices*
- *ISO10993-7:2008/AMD-1:2019 – Biological evaluation of medical devices – Ethylene Oxide sterilization residuals*

Shelf Life and Sterile Barrier Packaging: The shelf life and sterile barrier packaging of the single-use disposable devices were evaluated per the following standards:

- *ASTM F1980-16 – Standard guide for accelerated aging of sterile barrier systems for medical devices*
- *ASTM F 1929-15 – Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration*
- *ASTM F88/F88M-15: Standard Test Method for Seal Strength of Flexible Barrier Materials*
- *ISO 11607 – Packaging for terminally sterilized medical devices*

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(s) and standards:

- *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 10993-1:2018 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*
- *ISO 10993-5:2009 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*
- *ISO 10993-10:2010 - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization*
- *ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity*
- *ISO 10993-23:2021 - 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 to the following standards:

- *IEC 60601-1:2005 (Third edition) + CORR. 1: 2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint) – Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)*
- *IEC 60601-1-2:2014 – Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*
- *IEC 60601-2-10:2016 – Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of*

nerve and muscle stimulators

- *IEC 60601-2-2:2017 - Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

Software

Software was developed, tested, and verified per FDA's 2023 Guidance for the Content of Premarket Submissions for Device Software Functions..

Results of the updated software 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, patient-manual controlled-switch, and foot switch operation 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. Updated V&V testing was performed on the modified device to confirm the electrical stimulation output parameters (in accordance with FDA's 1999 Guidance on Powered Muscle Stimulator 510(k)s) as well as the accuracy of the added temperature sensors. 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 was executed according to FDA's 2023 Guidance on General Considerations for Animal Studies Intended to Evaluate Medical Devices.

8. Conclusion

Based on the same Indications for Use, similar characteristics as the predicate, and performance testing, the Legend X Platform with modified applicators raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety, effectiveness, and performance.