DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 13, 2017

Pollogen Ltd.
% Ms. Elissa Burg
Regulatory Consultant
BioVision Ltd.
Had Nes 183
Had Nes, Israel 1295000

Re: K171359
Trade/Device Name: Pollogen Legend+ System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 22, 2017
Received: August 29, 2017

Dear Ms. Burg:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171359

Device Name
Pollogen Legend+™ System

Indications for Use *(Describe)*
The Pollogen Legend+™ System is 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 RF Energy (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.

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510(k) SUMMARY

Pollogen Ltd.'s Pollogen Legend$^{+™}$ System

Applicant's name: Pollogen Ltd.
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Date Prepared: April 27, 2017

Name of Device: Pollogen Legend$^{+™}$ system

Common or Usual Name: Electrosurgical cutting and coagulation device and accessories

Classification: Product Code: GEI
Regulation No: 21 C.F.R. §878.4400
Class: II
Classification Panel: General & Plastic Surgery

Predicate Devices:

- Pollogen Ltd., Apollo (K111026)
- Pollogen Ltd., Surgen U (K131758)

Intended Use / Indications for Use

The Pollogen Legend$^{+™}$ system is 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 RF Energy (Applicators 1-3).

Device Description

The Pollogen Legend$^{+™}$system delivers bipolar radiofrequency (RF) electrical current to the skin surface for dermatological procedures requiring ablation and resurfacing of the skin. The physician can control the parameters of the device through a user interface.

The system consists of:

- Main Unit (includes the Controller);
- Control Panel (User Interface);
- RF Generator;
- VO (VoluDerm) Treatment Applicator;
- Treatment Applicators 1-3 (TriPollar);
- Foot Switch;
- Patient-Controlled Manual Switch.

The device generates RF energy, which is applied to the skin. The VO (VoluDerm Energy) treatment applicator applies pulses of bipolar RF energy that flows between electrodes to create micro-ablation points on the skin via an array of multi-electrode pins.

The TriPollar treatment Applicators 1-3 apply bipolar RF energy that flows between electrodes on the skin. The three applicators differ in size and configuration and are indicated for treatment of various size facial areas. The operator can adjust treatment parameters, such as the power level and treatment time from the user interface on the Main Unit. The Applicator is applied with a little pressure and a rubbing/massaging technique (linear, circular, etc., depending on the area). The applicator should be moved continuously on the skin. No active cooling of the electrodes or the skin is required.

Technological Characteristics

The Pollogen Legend$^{+™}$system consists of a console, Applicators 1-3 (TriPollar) and VO (VoluDerm) hand held applicators, and disposable tips. It is designed to deliver bipolar radiofrequency electrical current to the skin.

Performance Data

Pollogen conducted several performance tests to demonstrate that the Pollogen Legend$^{+™}$ system complies with performance standards and that it functions as intended.

- Tripollar RF Energy (Accuracy test) was performed to validate Pollogen Legend$^{+™}$ system's power control and accuracy in reference to the user's input (Applicators 1-3).

- VoluDerm Energy Electrical Verification was performed to validate the Pollogen Legend$^{+™}$ system power control and accuracy in reference to the user's input, and verify the maximum energy per pin is not higher than 62 mJ (VO Applicator).

- VO disposable tip drop test Verification was performed to validate disposable tip packages durability after drop tests.

- Performance testing of the Voluderm Applicator Tips was done to validate that the VO tips, gen 12 and gen 36, are capable of performing 800 pulses while electrode pins and return were not affected and remain fully intact.

- VO disposable tip electrode pins mechanical strength Verification was performed to validate disposable tip electrode pins withstand the specified applied force.

Electrical safety and compatibility testing was done to validate the Pollogen Legend$^{+™}$ system's power control and accuracy in reference to the user's input.

In all instances, the Pollogen Legend$^{+™}$ system functioned as intended and observations were as expected.

Performance Standards

The Pollogen Legend$^{+™}$ system complies with the following performance standards:

- IEC/EN 60601-1 Edition 3.1 - Medical Electrical Equipment Part 1: General requirements for safety (2005/AMD:2012).

- IEC/EN 60601-2-2 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 (2009)

- IEC 60601-1-2 Medical Electrical Equipment – Part 2. Collateral standard: Electromagnetic compatibility - Requirements and tests (2007, Ed. 3).

- IEC 60601-2-2 Medical electrical Equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment (2006); clauses 36.201 (Emission) & 36.202 (Immunity)

- IEC 62304 Medical device software – Software life cycle processes (2006/AMD2015)

- ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing

- ISO 10993-7:2008 - Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals

Substantial Equivalence

The Pollogen Legend$^{+™}$system is as safe and effective as Pollogen's apollo device (K111026) for applicators 1-3 (TriPollar) and as safe and effective as Pollogen's Surgen U device (K131758) for the VO (VoluDerm) applicator. The Pollogen Legend$^{+™}$ system has the same intended use and indications for use and similar technological characteristics and principles of operation as its predicate devices per each applicator. No technological differences exist between the Pollogen Legend$^{+™}$ system and its predicate device per each applicator. Performance data demonstrate that the Pollogen Legend$^{+™}$ system is as safe and effective as its predicate devices. Thus, the Pollogen Legend$^{+™}$ system is substantially equivalent to its predicate devices.