510(k) SUMMARY

MAY 14 2014

Pollogen Ltd.'s STOP U System

Applicant's name: Pollogen Ltd.
6 Kaufman St.
Gibor House, P.O.B. 50320
Tel Aviv
ISRAEL 6801298
Tel. (972)3-510-4110
Fax (972)3-510-4112

Contact Person: Jonathan S. Kahan
Partner
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004
Tel. (202) 637-5794
Fax (202) 637-5910

Date Prepared: May 13, 2014

Name of Device: STOP U device

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)

Device Description

The STOP™ U device delivers RF current into the skin to generate heat through electrical impedance in the dermis and subcutaneous layers.
The device consists of the following components and accessories: The STOP U device (applicator unit), the STOP U Power Supply and the STOP Preparation Gel.

Intended Use / Indications for Use

Pollogen's STOP U is intended for use in the non-invasive treatment of mild to moderate facial wrinkles and rhytides.

Technological Characteristics

The TriPollar™ STOP U device delivers RF energy at a frequency of 1 MHz and a maximum output RMS power of 5.7 watts into the skin through its electrodes. The device generates heat through electrical impedance in the dermis and subcutaneous layers. The temperature sensor, located between the electrodes constantly monitors the skin temperature and disables RF transmission once the desired skin temperature is obtained.

Performance Data

Pollogen conducted several performance tests to demonstrate that the STOP U system complies with performance standards and that it functions as intended:

- STOP U Electrical Verification was done to validate the STOP U power control and accuracy in reference to the user's input.
- The STOP U software was validated as required.

In all instances, the STOP U system functioned as intended and observations were as expected..

Performance Standards

The STOP U system complies with the following performance standards:

- EN/IEC 60601-1 Medical Electrical Equipment-Part 1: General Requirements for Safety. Collateral Standard: Safety Requirements for Medical Electrical Systems.
- EN/IEC 60601-1-2 Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.
- EN/IEC 60601-2-2 - Safety of high frequency surgical equipment.

Clinical performance data

A study was conducted in order to evaluate the safety and efficacy of the STOP U device for treatment of wrinkles and rhytides. Altogether, 40 subjects were enrolled in the study. Subjects were treated for improvement of facial wrinkles appearance and were followed for 3 months post last treatment. In order to assess safety, adverse events occurrence was monitored before and after each treatment and at follow up visits. In order to evaluate treatment efficacy, pre and post treatment photos were introduced to three uninvolved physicians for blinded evaluation based on Fitzpatrick Wrinkle and Elastosis scale.

Over 80% of the subjects showed at least one grade improvement in Fitzpatrick wrinkle score at three months follow-up post treatment based on objective evaluations of the baseline and three months follow-up photographs. There were no incidences of adverse effects or complications. As expected, mild to moderate erythema and mild edema were detected at the site of treatment immediately after treatment. All cases resolved without treatment within few hours. Treatment was well tolerated with minimal to no pain in the majority of study subjects. The data reported in this study clearly indicates that the Stop U provides a safe and effective treatment for facial wrinkles.

Substantial Equivalence

The STOP U system is as safe and effective as Pollogen Ltd.'s apollo device (K111026). The STOP U system has the same intended use and indications for use and similar technological characteristics and principles of operation as its predicate device. The minor technological differences between the STOP U system and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the STOP U system is as safe and effective as its predicate device. Thus, STOP U is substantially equivalent.

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

May 14, 2014

Pollogen Ltd.
% Mr. Jonathan S. Kahan
Hogan Lovells US LLP
555 Thirteenth Street, Northwest
Washington, District of Columbia 20004

Re: K140255
Trade/Device Name: STOP U
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 28, 2014
Received: March 28, 2014

Dear Mr. Kahan:

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 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" (21CFR 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 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 yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting 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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

Indications for Use

510(k) Number *(if known)*
K140255

Device Name

STOP U

Indications for Use *(Describe)*

Pollogen's STOP U is intended for use in the non-invasive treatment of mild to moderate facial wrinkles and rhytides.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S