June 19, 2019

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

Re: K182774
Trade/Device Name: STOP U (Packed Black USA), STOP U (Packed White USA)
Regulation Number: 21 CFR 878.4420
Regulation Name: Electrosurgical Device for Over-The-Counter Aesthetic Use
Regulatory Class: Class II
Product Code: PAY
Dated: May 8, 2019
Received: May 9, 2019

Dear Elissa 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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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 Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

V. INDICATIONS FOR USE STATEMENT

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)*

K182774

Device Name
STOP U

Indications for Use *(Describe)*

The STOP U device is intended for use in the non-invasive treatment of mild to moderate facial wrinkles for adult users who have Fitzpatrick Skin Types II-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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

VI.

510(k) SUMMARY

Pollogen Ltd.'s STOP U Device

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: Elissa Burg
Regulatory Consultant
BioVision Ltd.
Had Nes 183
Israel 1295000
Tel. (972) 526633572
Fax (972) 4-6827312

Date Prepared: September 25, 2018

Name of Device: STOP U

Common or Usual Name: Electrosurgical device for over-the-counter aesthetic use

Classification: **Product Code:** PAY
Regulation No: 21 C.F.R. §878.4420
Class: II
Classification Panel: General & Plastic Surgery

Predicate Devices

- Pollogen Ltd., STOP U (K140255)
- Endymed Ltd., NEWA (DEN150005)

Intended Use / Indications for Use

The STOP U device is intended for use in the non-invasive treatment of mild to moderate facial wrinkles for adult users who have Fitzpatrick Skin Types II-IV.

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.

Technological Characteristics

The 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 device complies with performance standards and that it functions as intended.

- STOP U Electrical safety and compatibility testing was performed to validate the STOP U power control and accuracy in reference to the user's input.

- STOP U over-heating safety testing was performed to validate the conformity with the STOPU's design requirements and specifications for its temperature sensor and profile in reference to the user's input.

- The STOP U software was validated as required.

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

Performance Standards

The STOP U device complies with the following performance standards:

- IEC/EN 60601-1 Edition 3.1 - Medical Electrical Equipment Part 1: General requirements for safety (2005) and A1:2012.

- IEC 62304 Medical device software – Software life cycle processes (2006, Ed. 1/AMD A1:2015)

- 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 Ed.5) sections 202.6.1 (Emission) & 202.6.2 (Immunity).

- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (2014, Ed. 4).

- IEC 60601-1-11:2015 (2nd edition), Medical electrical equipment Part 1-11 – General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

- IEC 60601-1-6 Medical Electrical Equipment Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (2010/AMD2013)

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

- ISO 15223-1:2016– Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied — Part 1: General requirement

- ISO 14971:2012 - Medical devices – Application of risk management to medical devices

Clinical performance data

Safety & Effectiveness

The effect of treatment of mild to moderate facial wrinkles using the STOP U was tested in a clinical trial that was conducted to support the clearance of the prescription version of the STOP U device (K140255). Since the over-the-counter (OTC) version of the STOP U device is identical to the prescription version, this data is also applicable to support the safety and effectiveness of the OTC device.

Altogether, 40 subjects (37 female and 3 male) 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 a 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.

Usability, Self-selection & Labeling Comprehension

Furthermore, Pollogen conducted a usability study for the STOP U device which was divided into two stages:

1. Stage one – Self-Selection Study of the STOP U Device;
2. Stage two – Human Factors Validation of the Pollogen STOP U Device.

The Self -Selection study using the final STOP U packaging design produced a correct self-selection rate that met Pollogen's goal. The final packaging design promotes correct self-selection and adequately explains user eligibility to potential users in the real world.

61 subjects (39 female and 22 male) which had successfully identified themselves as potential device users participated in the Human Factors validation with 100% success rate. These results indicated that the design of the STOP U and its associated instructional materials facilitated safe use of the device.

Substantial Equivalence

The following table compares the STOP U device to the predicate devices with respect to intended use, technological characteristics and principles of operation, providing detailed information regarding the basis for the determination of substantial equivalence.

	STOP U Proposed Device	**STOP U (K140255)**	**Newa (DEN150005)**
Manufacturer	Pollogen® Ltd.	Pollogen® Ltd.	Endymed™
Device Class	Class II	Class II	Class II
Regulation Description	Electrosurgical device for over-the-counter aesthetic use	Electrosurgical cutting and coagulation device and accessories	Electrosurgical device for over-the-counter aesthetic use
Regulation Number	21 C.F.R. 878.4420	21 C.F.R. §878.4400	21 C.F.R. 878.4420
Product Code	PAY	GEI	PAY
Intended Use/Indications for Use	The STOP U device is intended for use in the non-invasive treatment of mild to moderate facial wrinkles for adult users who have Fitzpatrick Skin Types II-IV.	The STOP U device is intended for use in the non-invasive treatment of mild to moderate facial wrinkles and rhytides.	The EndyMed Newa™ is an over-the-counter home use device intended for non-invasive treatment of mild to moderate facial wrinkles for adult women with Fitzpatrick Skin Types I-IV
Deep tissue Heating Electromagnetic Energy	RF	RF	RF
Modes of Operation	RF Bipolar Energy	RF Bipolar Energy	RF Bipolar Energy
Nominal Operating RF Power (200 Ohms)	5.7W	5.7W	10W
RF Carrier Frequency	1MHz	1MHz	675KHz

	STOP U Proposed Device	STOP U (K140255)	Newa (DEN150005)
Waveform	Sinusoid	Sinusoid	Square
Applicator Effective Area	1 cm^2	1 cm^2	0.9 X 1.5 = 1.35 cm^2
Total Power Density (fluence)	5.7 W/cm^2	5.7 W/cm^2	10 W/cm^2
Output Voltage	8V DC	8V DC	9V DC
Dimensions	H=134mm; L=51mm; W=32mm	H=134mm; L=51mm; W=32mm	120mm X 73mm X 37mm
Weight	85 gr	85 gr	70 gr
RF Energy Emission Indicator	Yes (Temp. sensor)	Yes (Temp. sensor)	Yes (Temp. sensor & motion sensor)
Energy Source	100-240V, 50-60Hz, 600mA	100-240V, 50-60Hz, 600mA	100-240V, 50-60Hz, 800mA
Heating Levels	1	1	2
Electrodes	4	4	6
Biocompatibility	All parts that are in contact with patient comply with the requirements of ISO 10993-1	All parts that are in contact with patient comply with the requirements of ISO 10993-1	All parts that are in contact with patient comply with the requirements of ISO 10993-1
Software	Verified and validated according to the FDA guidance	Verified and validated according to the FDA guidance	Verified and validated according to the FDA guidance
Intended Operating Environment	Home Use Device	Prescription Use Device	Home Use Device
Intended Operator	Lay Person	Healthcare professionals	Lay Person
Testing	Electrical safety, EMC, & Usability Study	Electrical safety, EMC & Clinical Study	Electrical safety, EMC, Clinical & Usability Study

The subject STOP U device is as safe and effective as Pollogen's STOP U device (K140225) and Endymed's NEWA (DEN150005). The Pollogen STOP U device has the same intended use and indications for use and similar technological characteristics and principles of operation as its predicate devices. Performance data demonstrate that the STOP U device is as safe and effective as its predicate devices. Thus, the STOP U device is substantially equivalent to its predicate devices.