May 4, 2023

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

Re: K220322
Trade/Device Name: Pollogen STOP U Model UXV Device
Regulation Number: 21 CFR 878.4420
Regulation Name: Electrosurgical Device For Over-The-Counter Aesthetic Use
Regulatory Class: Class II
Product Code: PAY
Dated: April 3, 2023
Received: April 3, 2023

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.05.04 09:04:30 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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and Infection Control Devices
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)*
K220322

Device Name
STOP U Model UXV Device

Indications for Use *(Describe)*
The STOP U Model UXV device is intended for use in the non-invasive treatment of mild to moderate facial wrinkles for adult users who have Fitzpatrick Skin Types I-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.

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K220322 - 510(k) SUMMARY

Pollogen Ltd.'s STOP U Model UXV Device

Applicant's name: Pollogen Ltd.
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Date Prepared: April 3, 2023

Name of Device: STOP U Model UXV

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 Device: Pollogen Ltd., STOP U Model UXV (K203665)

Intended Use / Indications for Use

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

Device Description

The STOP U Model UXV 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 Model UXV device (applicator unit), the STOP U Model UXV Power Supply and the STOP Preparation Gel.

Technological Characteristics

The TriPollar™ STOP U Model UXV device delivers RF energy at a frequency of 1 MHz (+/- 10%) and a maximum output RMS power of 5.7 watts (+/- 10%) into the skin through its electrodes. The device generates heat through electrical impedance in the dermis and subcutaneous layers. The temperature sensor located in the electrodes area constantly monitors the skin temperature and disables/reduces RF transmission once the maximal skin temperature is obtained.

Performance Data

Pollogen conducted several performance tests to demonstrate that the STOP U Model UXV device complies with performance standards and that it functions as intended.

- Verification test demonstrating that the STOP U Model UXV meets the system's technical specification for the max RF power output.

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

- The STOP U Model UXV software was validated as required.

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

Performance Standards

The STOP U Model UXV 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 60601-1-6 Medical Electrical Equipment Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (2010/AMD2013).

- 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/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 (Edition 6.0 2017-03).

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

- 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).

- 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 14971:2007 - Medical devices – Application of risk management to medical devices.

8. Cleaning / Disinfection, Shelf Life and Biocompatibility

The STOP U Model UXV is a reusable device which is required to be cleaned following each use according to a validated cleaning procedure.
The device's cleaning instructions are based on the cleaning instructions of the predicate device due to the fact that both devices are made from the same materials and used similarly.

The shelf-life expectancy of the device is 7 years, similar to the predicate device.

The biocompatibility evaluation for the STOP U Model UXV device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1:
"Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

Pollogen has categorized its STOP U Model UXV device as: "Surface device, Skin Contact for limited contact duration", with contact duration of less than 24h.
Therefore, the battery of testing included the following tests: cytotoxicity, sensitization and irritation tests.

The body contact materials are biocompatible per:
- ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

Clinical performance data

Safety & Effectiveness

A Self-Selection study and Human Factors validation were conducted to demonstrate that users can safely and effectively self-select, set up and deliver treatment with the previously cleared STOP U (K182774).
The Self -Selection study using the final packaging and 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 which had successfully identified themselves as potential device users participated in the Human Factors validation with a 100% success rate. These results indicated that the design of the STOP U (K182774) which is similar to the subject STOP U Model UXV and its associated instructional materials facilitated safe use of the device.

Additionally, a clinical study was conducted demonstrating the effect of the TriPollar technology for mild to moderate facial wrinkles and rhytides while using the FDA-cleared STOP U device for prescription use (K140255). This study substantiates the safety and effectiveness of the TriPollar Technology for wrinkle reduction incorporated into the subject STOP U Model UXV and thus substantiates the safety and effectiveness of the subject STOP U Model UXV.

Substantial Equivalence

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

	Proposed Device: Modified STOP U Model UXV	**Predicate Device: STOP U Model UXV (K203665)**
Manufacturer	Pollogen® Ltd.	Pollogen® Ltd.
Device Class	Class II	Class II
Regulation Description	Electrosurgical device for over the-counter aesthetic use	Electrosurgical device for over the-counter aesthetic use
Regulation Number	21 C.F.R. 878.4420	21 C.F.R. 878.4420
Product Code	PAY	PAY
Intended Use / Indications for Use	The STOP U Model UXV device is intended for use in the non-invasive treatment of mild to moderate facial wrinkles for adult users who have **Fitzpatrick Skin Types I-IV**	The STOP U Model UXV 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**
Deep tissue Heating Electromagnetic Energy	RF	RF
Modes of Operation	RF Bipolar Energy	RF Bipolar Energy
Nominal Operating RF Power (200 Ohms)	5.7W (+/- 10%)	5.7W (+/- 10%)
RF Carrier Frequency	1MHz (+/- 10%)	1MHz (+/- 10%)

	Proposed Device: Modified STOP U Model UXV	Predicate Device: STOP U Model UXV (K203665)
Waveform	Sinusoid	Sinusoid
Applicator Effective Area	1 cm^2	1 cm^2
Total Power Density (fluence)	5.7 W/cm^2 (+/- 10%)	5.7 W/cm^2 (+/- 10%)
Output Voltage	8V DC	8V DC
Output Current	1.5A	1.5A
Dimensions	H=134mm; L=51mm; W=32mm	H=134mm; L=51mm; W=32mm
Weight	85 gr	85 gr
RF Energy Emission Indicator	Yes (Temp. sensor)	Yes (Temp. sensor)
Energy Source	100-240V, 50-60Hz, 0.4A	100-240V, 50-60Hz, 0.4A
Heating Levels	1	1
Electrodes	4	4
Electrodes Diameter	6mm	6mm
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
Software	Verified and validated. according to the FDA guidance	Verified and validated. according to the FDA guidance

	Proposed Device: Modified STOP U Model UXV	Predicate Device: STOP U Model UXV (K203665)
Intended Operating Environment	Home Use Device	Home Use Device
Intended Operator	Lay Person	Lay Person
Testing	Electrical safety & EMC, & Usability Study	Electrical safety, EMC, & Usability Study

Conclusion:

The modified STOP U Model UXV device is as safe and effective as its predicate, Pollogen's STOP U Model UXV device (K203665). The modified STOP U Model UXV device has the same intended use and identical technological characteristics and principles of operation as its predicate. Clinical and Performance data demonstrated that the minor difference in the indications for use of the STOP U Model UXV device does not raise any issues of safety or effectiveness in comparison to the predicate device. Thus, the STOP U Model UXV device is substantially equivalent to its predicate, Pollogen's STOP U Model UXV device (K203665).