March 6, 2024

EL Global Trade Ltd.
Sivan Fishman
RA/QA Manager
6th Ha-Gavish St.
Netanya, 4250706
Israel

Re: K232424
Trade/Device Name: CurrentBody Skin RF
Regulation Number: 21 CFR 878.4420
Regulation Name: Electrosurgical Device For Over-The-Counter Aesthetic Use
Regulatory Class: Class II
Product Code: PAY
Dated: February 5, 2024
Received: February 6, 2024

Dear Sivan Fishman:

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.

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.03.06 15:31:16 -05'00'

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
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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)*
K233705

Device Name
CurrentBody Skin RF (ST030)

Indications for Use *(Describe)*
The CurrentBody Skin RF (ST030) device is an over-the-counter home-use device intended for non-invasive treatment of mild to moderate facial wrinkles for adults with 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.

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

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K232424 510(k) Summary
EL Global Trade Ltd. For *Currentbody Skin RF*

1. DATE PREPARED: March 3RD, 2024

2. 510(K) OWNER NAME

EL Global Trade Ltd.

6th Ha-Gavish St., Netanya 4250706, Israel.

Phone: +972-9-7889069, Fax: +972-9-7734831.

Contact person name: Sivan Fishman, RA/QA Manager

Phone: +972-54-5223677, Fax: +972-9-7734831

E mail: sivanf@sensica.com

3. DEVICE NAME

Common/Usual Name: OTC device for skin tightening based on RF

Proprietary/Trade Name: *CurrentBody Skin RF*

Model Name: *ST030*

Classification: EL Global Trade Ltd.'s *CurrentBody Skin RF* device has been classified as **Class II** device under the following classification names:

Classification Name	Product Code	Regulation Number	Panel
Electrosurgical device for over-the-counter (OTC) aesthetic use	PAY	878.4420	General and Plastic Surgery

4. PREDICATE DEVICES

EL Global Trade Ltd.'s *CurrentBody Skin RF* device is substantially equivalent to the following Predicate Device:

Pollogen Stop U Model UXV device,

cleared under 510(k) number **K220322** on May 4th, 2023.

5. DEVICE DESCRIPTION

The *CurrentBody Skin RF device* is an OTC, home-use hand-held device generating pulses of radiofrequency (RF) energy that are emitted into the skin. RF energy heats the tissue to improve the appearance of wrinkles and rhytides. It is a non-invasive, non-ablative device consisting of:

- User Interface
- Programmable logic controller (PLC, microcontroller) embedded in PCBA
- RF power module
- Power Supply
- RF electrodes

The PLC (on the PCBA) is a specially configured software that, combined with hardware circuits, provides the operational and safety function of the system. The RF power module provides RF energy to the active tip electrodes, producing a signal of 1MHz frequency (power limited by hardware). This device is supplied non-sterile.

Technical specifications:

- Maximal power output: 5±1 Watt.
- Frequency: 1±0.05 MHz
- Maximal temperature allowed: 40.5 ± 0.5^0C.

6. INTENDED USE/ INDICATIONS FOR USE

The *CurrentBody Skin RF device* is an over-the-counter home use device intended for non-invasive treatment of mild to moderate facial wrinkles for adults with Fitzpatrick skin types I-IV.

7. NON-CLINICAL (BENCH) PERFORMANCE DATA

The following performance data (bench tests) were provided in support of the performance, safety and efficacy of the *CurrentBody Skin RF* device as well as the substantial equivalence determination.

Safety Bench Tests and Verification & Validation (V&V) Summary

- **Over-heating safety**. The two redundant thermistors embedded in the device constantly measure the skin temperature and constantly alter the power emitted to maintain the temperature constant within the target treatment temperature range (maximal temperature of 40.5 ± 0.5^0C). **Power accuracy**. The device was validated on a 200 Ω load, which is appropriate as the reference of the average load of the user. The measured total power was within the error margin, indicating that the device met the acceptance criteria.

- **Parameter validation**. The device was tested for its varied parameters, including radio frequency, pulse cycle, wave form and pulse duration. All results were within the acceptance criteria.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the *CurrentBody Skin RF* device. The device complies with:

- IEC 60601-1:2005/EN 60601-1:2006, General safety standard: safety requirements for medical electrical systems.

- IEC 60601-1-2:2014/EN 60601-1-2:2015, Medical electrical equipment Part 1-2 - General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.
- IEC 60601-1-11:2015, Medical electrical equipment Part 1-11 – Requirements for the medical electrical equipment and medical electrical systems used in the home healthcare environment.
- 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 Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern because inadvertent software errors could result in skin burns to the user.

Human Factors Validation Testing

A Self-Selection and Human Factors validation study was performed to demonstrate that users can safely and effectively self-select, prepare and perform treatment with the CurrentBody Skin RF device.

Thermal Effects on porcine belly skin

In order to provide further evidence for the equivalence of the spatio-temporal heating profile of the subject and predicate devices, a bench experiment was conducted in porcine belly skin samples instrumented with multiple calibrated

temperature probes. Measurements showed comparable (near identical) spatio-temporal tissue heating between the subject and predicate devices.

Thus, the CurrentBody Skin RF device can be regarded as thermally equivalent to the approved Pollogen STOP U Model UXV device and no risks are raised regarding the safety and efficacy of the device.

8. PERFORMANCE TESTING - ANIMAL

No animal testing was performed with the subject device.

9. CLEANING, STERILIZATION, SHELF LIFE AND BIOCOMPATIBILITY

The *CurrentBody Skin RF device* is a non-sterile, reusable device, intended for a single user. The device 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 5 years, similarly to the predicate device.

The biocompatibility evaluation for the *CurrentBody Skin RF* device was conducted in accordance with the FDA guidance "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" September 8, 2023, 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.

10. CLINICAL PERFORMANCE DATA

No clinical testing was performed with the subject device, as it is substantially equivalent to the predicate device, and thus requires no additional clinical data to prove its safety and efficacy.

11. SUBSTANTIAL EQUIVALENCE

The indications for use and technological characteristics of the *CurrentBody Skin RF* device are substantially equivalent to the indications for use and technological characteristics of the predicate device, as can be seen in the technology comparison table below.

The design and components of both devices (i.e., power supply, RF generator and controller) are similar. The performance specifications of the *CurrentBody Skin RF* (i.e., RF frequency and electrical power) are substantially equivalent to those of the predicate device. The safety features and compliance with safety standards of both are similar. The body contact materials are similar. The minor differences in the technological characteristics do not raise new safety or effectiveness concerns and are demonstrated to be substantially equivalent through relevant performance tests. Furthermore, the *CurrentBody Skin RF* device has qualified with varied performance tests, including software validation testing, electrical and mechanical safety testing according to IEC 60601-1, electromagnetic compatibility testing according to IEC 60601-1-2, compatibility as medical electrical equipment for home healthcare environment according to 60601-1-11, and high frequency of surgical equipment according to IEC 60601-2-2. The performance tests demonstrated that the device specifications meet the system requirements and do not raise new safety or effectiveness concerns.

Feature	**EL Global** ***CurrentBody Skin RF*** [K232424] *New Device*	**Pollogen** ***STOP U Model UXV*** [K220322] *Predicate Device*
Manufacturer	El Global Trade Ltd.	Pollogen Ltd.
Device Class	Class II	Class II
Classification Panel	General and Plastic Surgery	General and Plastic Surgery
Product code	PAY	PAY
Regulation number	21 CFR 878.4420	21 CFR 878.4420
Device type	Over-The-Counter Radiofrequency Coagulation Device For Wrinkle Reduction	Over-The-Counter Radiofrequency Coagulation Device For Wrinkle Reduction
Regulation description	Electrosurgical device for over-the-counter aesthetic use	Electrosurgical device for over-the-counter aesthetic use
Intended use	The CurrentBody Skin RF is an over-the-counter home use device intended for non-invasive treatment of mild to moderate facial wrinkles for adult users who have Fitzpatrick Skin Types I-IV.	The Stop U Model UXV Skin RF is an over-the-counter home use device intended for non-invasive treatment of mild to moderate facial wrinkles for adult users who have Fitzpatrick Skin Types I-IV.
Deep Tissue Heating Electromagnetic Energy	RF	RF
Mode of Operation	RF Bipolar Energy	RF Bipolar Energy
Mechanism of Operation	The device is a home-use hand-held device generating pulses of RF energy that is emitted into the skin. RF energy heats the tissue to improve the appearance of wrinkles and rhytides. It is a non-invasive and non-ablative device.	The device is a home-use hand-held device generating pulses of RF energy that is emitted into the skin. RF energy heats the tissue to improve the appearance of wrinkles and rhytides. It is a non-invasive and non-ablative device.
RF Carrier Frequency	1 MHz RF (Bi-polar)	1 MHz RF (Bi-polar)
Operating RF Power (200 Ohms)	5W ± 1	5.7W ± 10%
Waveform	Sinusoid	Sinusoid
Number of electrodes	4 round electrodes (2 pairs of Bi-polar electrodes).	4 round electrodes (2 pairs of Bi-polar electrodes).
Electrode Diameter	6mm	6mm
Intended population	Adult healthy men and women (Fitzpatrick skin type I-IV) who desire to reduce facial wrinkles.	Adult healthy men and women (Fitzpatrick skin type I-IV) who desire to reduce facial wrinkles.

Feature	EL Global ***CurrentBody Skin RF*** [K232424] *New Device*	Pollogen ***STOP U Model UXV*** [K220322] *Predicate Device*
Intended Operating Environment	Home Use Device	Home Use Device
Intended Operator	Lay Person	Lay Person
Dimensions, (LXHXW) [mm^3]	145 X 45 X 42	134 X 51 X 32
Weight [gr]	96	85
Applicator Effective Area	1 cm^2	1 cm^2
Total Power Density (fluence)	5 W/cm^2 ± 1	5.7 W/cm^2 ± 10%
Distance Between Electrodes	1 cm	1 cm
Penetration Depth	~0.5 cm	~0.5 cm
Body contact materials	ABS plastic shell. Chrome coated electrodes.	ABS plastic shell. Chrome coated electrodes.
Heating Levels	1 energy level (5 ± 1 W)	1 energy level (5.7W ± 10%).
RF Energy Emission Indicator	Yes (Temperature sensors)	Yes (Temperature sensor)
Electrical requirements	100-240 V, 50-60 Hz 9 V, 1.5 A	100-240 V 50-60 Hz 8 V, 1.5 A
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.
Testing	Electrical safety & EMC, usability study.	Electrical safety & EMC, usability study.

12. CONCLUSIONS

Based on the performance testing and comparison to predicate devices, the *CurrentBody Skin RF* device is substantially equivalent to the previously cleared *Pollogen Stop U Model UXV* predicate device.