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

October 13, 2017

EL Global Trade Ltd
Dr. Yael Liebes
RA/QA Manager
8 Tzoran St., P.O. Box 8242
Netanya, Israel 4250608

Re: K172181
Trade/Device Name: micro PL
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OHT, ONF
Dated: July 16, 2017
Received: July 19, 2017

Dear Dr. Liebes:

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172181

Device Name
micro IPL

Indications for Use *(Describe)*

The micro IPL is an over the counter device intended for the removal of unwanted body and/ or facial hair in adults. The micro IPL is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as a long-term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of treatment regimen.

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."

SECTION 05

MICRO IPL DEVICE

AN OVER-THE-COUNTER HOME USE DEVICE INTENDED FOR HAIR REDUCTION BASED ON INTENSE PULSED LIGHT (IPL)

510(K) SUMMARY

510(K) SUMMARY FOR EL GLOBAL TRADE LTD.'S MICRO IPL

DATE PREPARED: JULY 16TH, 2017

1. 510(K) OWNER NAME

EL Global Trade Ltd.

Tzoran 8th st, P.O.Box 8242, Netanya 4250608, Israel.

Phone: +972-9-7889067, Fax: +972-9-7734831.

Contact person name: Dr. Yael Liebes-Peer, RA/QA Manager

Phone: +972-9-7889067, Fax: +972-9-7734831, E mail: yael@sensica.com

2. DEVICE NAME

Common/Usual Name: Light based hair removal devices

Proprietary/Trade name: *micro IPL*

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

Classification Name	Product Code	Regulation Number	Panel
Light Based Over-The-Counter Hair Removal and Powered Light Based Non-Laser Surgical Instrument With Thermal Effect	OHT and ONF	878.4810	General and Plastic Surgery

3. PREDICATE DEVICES

EL Global Trade Ltd.'s *micro IPL* device is substantially equivalent to the following Predicate Devices:

3.1 EL Global Trade Ltd.'s *sensiLight Mini* device,

cleared under 510(k) numbers: **K161089** at July 8, 2016 and **K140527** at July 31, 2014.

3.2 Stetic Medical Aesthetics Development (Shenzhen) Co. Ltd.'s Duo model: IPL-HH380-IT,

cleared under 510(k) number **K161565** at September 1, 2016.

4. DEVICE DESCRIPTION

The micro IPL device is pulsed light hair removal device. Light-based hair removal is based on the theory of selective photothermolysis in which optical energy is used to disable hair growth. The micro IPL device is composed of a hand held applicator and an external power supply. The spot size (treatment area) in the micro IPL device is 3 cm^2.

The device contains a lamp, a skin proximity sensor and a skin pigmentation sensor to detect appropriate skin tones. If the micro IPL is not properly applied (in full contact with the skin) or user skin tone is too dark/tanned, the micro IPL will not trigger a pulse.

Body contact materials were evaluated for biocompatibility with accordance to *FDA's Memorandum – #G95 1, May 1, 1995* and *ISO 10993-1:2009.*

5. INTENDED USE

The micro IPL is an over the counter device intended for removal of unwanted body and/or facial hair in adults. The micro IPL is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as a long-term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of treatment regimen.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The micro IPL device relies on the same technology as both predicate devices: Intense Pulsed Light (IPL). The safety and efficacy of IPL treatment for hair reduction are governed by the following parameters:

- Wavelength of the emitted light (spectrum): Defines the interaction with specific chromophores (the part of the molecule responsible for its color) such as melanin, hemoglobin and water. The micro IPL device and the predicate devices utilize the same spectrum (475 – 1200nm for both micro IPL and sensiLight mini predicate device and 480-1200nm for the Duo predicate device).
- Fluence/flux – defines the energy per area (e.g. joules per cm^2) for the treatment. The micro IPL device and the predicate devices deliver exactly the same maximum energy (5 joules/cm^2).
- Pulse duration – Provides for an efficient heating of the target molecule but not its surroundings. The micro IPL device and the predicate device sensiLight mini utilize exactly the same pulse and similar to the Duo predicate device.

7. PERFORMANCE DATA (BENCH)

EL Global Trade Ltd's micro IPL has been successfully tested through bench and safety tests to support the determination of substantial equivalence with predicate devices.

The micro IPL device has been tested and complies with the following voluntary recognized standards:

1. IEC 60601-1:2012/EN 60601-1:2013 *(Ed. 3.1). Medical electric equipment-Part 1 General requirements for Basic safety and essential performance.*
2. IEC 60601-1-11:2015 (*Ed. 2). Medical electric equipment-Part 1: Collateral requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*.

3. IEC 60601-2-57:2011 (*Ed. 1). Medical electrical equipment-Part 2: Particular requirements for basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetics/aesthetic use*.
4. FCC part 15, Subpart B, Class B.
5. IEC 60601-1-2:2014 (*Ed. 4*) *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*.
6. IEC 62471:2006 (*Ed. 1)*. Photo-biological safety of lamps and lamp systems.
7. Software Validation was conducted according to IEC 62304:2006 - *Medical device software - Software life cycle processes*, and; FDA Guidance for the *Content of Pre-Market Submissions for Software Contained in Medical Devices*, dated May 11, 2005.
8. ISO 10993-1:2009 – *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* and with FDA's Memorandum – *#G95 1, May 1, 1995, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"* (Blue Book Memo G95-1).
9. ISO/IEC 14971:2007 (BS EN ISO 14971:2012) Medical devices – Application of risk management to medical devices.

Tests results are supporting all labeling claims in order to establish substantial equivalency.

8. CLINICAL PERFORMANCE DATA

No new clinical performance data is reported in this submission.

9. SUBSTANTIAL EQUIVALENCE

EL Global Trade Ltd.'s *micro IPL* is substantially equivalent to the predicate devices selected in terms of indication for use, technology, performances, place of use, patient population and nature of body contact.

The Substantial equivalence decision was received based on the following comparison with the predicate devices:

The design and components in the micro IPL, including the hand held applicator (with lamp, microcontroller, fan, skin color sensor, skin proximity sensor, indicator LEDs and operational button/s) are similar to the design and components found in the predicate devices (K161089, K140527 and K161565). The performance specifications (including light energy power, wavelength and pulse duration) are identical or similar. The safety features found in the devices are the same, including the skin color sensor, skin proximity sensor, etc. These safety features in the micro IPL device are substantially equivalent to the safety features found in the predicate devices. Any minor differences in the technological characteristics do not raise new safety or effectiveness concerns. Furthermore, the new micro IPL device underwent performance testing, including software validation testing and electrical and mechanical safety testing according to IEC 60601-1 and electromagnetic compatibility testing according to IEC 60601-1-2.

10. CONCLUSIONS

The evaluation of our device performances and comparison to predicate devices demonstrate that it is as safe and as effective as the predicate devices.