EL Global Trade Ltd.
Shachar Raz
RA/QA manager
8 Tzoran St, P.O. Box 8242
Netanya, 4250608 IL

March 18, 2019

Re: K183260
Trade/Device Name: Sensilight Pro / Pistol IPL
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: February 13, 2019
Received: February 19, 2019

Dear Shachar Raz:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Neil R Ogden -S

Digitally signed by Neil R Ogden -S
Date: 2019.03.18 15:22:34 -04'00'

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)*
K183260

Device Name
Sensilight Pro

Indications for Use *(Describe)*
The Sensilight Pro device is an over-the-counter device intended for the removal of unwanted body and/or facial hair. Sensilight Pro is also intended for permanent reduction in hair regrowth, defined as a long-term, stable reduction in the number of hairs regrowing when measured 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.

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SECTION 05

SENSILIGHT PRO

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 SENSILIGHT PRO

DATE PREPARED: MARCH 18, 2019

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. Shachar Raz, RA/QA manager

Phone: (213) 335-3521, E mail: ra_qa@homewellt.com

2. DEVICE NAME

Common/Usual Name: Light based hair removal devices

Proprietary/Trade name: *Sensilight Pro* or *Pistol IPL Device*

Classification: *Sensilight Pro* by EL Global Trade Ltd 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

Sensilight Pro by EL Global Trade Ltd. is substantially equivalent to the following Predicate Devices:

3.1 Home Well Trading LTD's *Beurer IPL 8500 Device*,

cleared under 510(k) number **K181734** on September 19, 2018

3.2 EL Global Trade Ltd.'s *sensiLight Mini*,

cleared under 510(k) number **K161089** on July 08, 2016

4. DEVICE DESCRIPTION

The Sensilight Pro is an intense pulse light hair reduction device. Phototherapy (Light-based) hair reduction is based on the theory of selective photothermolysis in which optical energy is used to disable hair re-growth. The Sensilight Pro is composed of a hand-held applicator and an external power supply/charger. The spot size (treatment area) in the Sensilight Pro is 4.5 cm^2 or 2 cm^2 (for large and precise treatment windows, respectively).

The device contains a lamp, a skin proximity and pigmentation sensor allowing application only on compatible skin tones and while in full contact with the treated area. If the Sensilight Pro is not properly applied (in full contact with the skin) or user skin tone is too dark/tanned, the device will provide indications on the faulty conditions and 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 Sensilight Pro is an over the counter device intended for removal of unwanted body and/or facial hair in adults. The Sensilight Pro 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

Sensilight Pro 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. Sensilight Pro and the predicate devices utilize the same spectrum as the Beurer IPL 8500 device (475-1200nm/550-1200nm) and the sensiLight mini predicate device (475-1200nm).
- Fluence/flux – defines the energy per area (e.g. joules per cm^2) for the treatment. Sensilight Pro 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. Sensilight Pro and the predicate devices has exactly the same pulse duration.

7. PERFORMANCE DATA (BENCH)

Sensilight Pro by EL Global Trade Ltd. has been successfully tested through bench and safety tests to support the determination of substantial equivalence with predicate devices.

Sensilight Pro 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.
10. CB IEC 62133:2012. *Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications.*
11. *UN 38.3 Recommendations on the Transport of Dangerous Goods, Model Regulations: Lithium Battery Transporation*

*For the complete list of tests and applicable standards see **Sensilight Pro Traceability Analysis, RD-18052 (Appendix C- subsection 038)**.

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

Human Factors Validation Testing

A human Factors Validation Testing was done to evaluate the HFE/ UE concerns, including label comprehension/self-selection and usability/user interface studies (one arm, simulated use and summative evaluation). In both studies, participants had received the labeling materials of the device, and given enough time to read it according to their own wish.

Labeling Comprehension/ Self Selection Study was aimed at demonstrating potential user comprehension of the device labeling (mainly the outer package) in order to decide if device use is appropriate for her. It had included three main questions regarding the intended use of the device, treatment areas and possibility to use the device according to the contraindication, with correct answers: „Yes“ or „No“, explenation and further validation by the moderator. A total of 25 participants, 4 men and 21 women, from age 23 to 75 years old (37 ± 14 years old) were enrolled to this study. Participants had different educational levels, as obtained by REALM testing with 28% below 9th grade level. All participants had met the inclusion/ exclusion criteria and signed ICF. 100% of the participants had reported correct answers, as further validated by the moderator (κ=1).

Usability/ User Interface Study was aimed at demonstrating the OTC user can correctly use the device, based on the labeling material for the intended aesthetic puspose. The study was focused on four use scenarios including 25 relevant tasks: “Getting to know the device and device set-up” (7 tasks), “self-preparation” (9 tasks), “device usage” (7 tasks) and “after usage” (2 tasks). None of the participants had required assistance from the moderator while performing the tasks. Altogether, all tasks were completed by 100% of the participants, and the success rate (pass criteria) was 100% per each task scenario.

In addition, in the follow up satisfaction questionnaire, filled by 18 of the 20 users, all participants (18) commented that the device usage is easy and clear with an average result of 4.4±0.2, using a 1-5 discrete scale (when 1 represents worst and 5 represents best). Labeling and instructions comprehension result was 4.1±0.2 and overall satisfaction was

at 4.1±0.2. Two participants found the device to be somewhat heavy and a single user found the trigger less mode to be unnecessary.

These two demonstrate that the intended OTC users can understand the package labeling, correctly choose the device and use it for the indicated aesthetic use, based solely on reading the lableing materials.

8. CLINICAL PERFORMANCE DATA

No new clinical performance data is reported in this submission.

9. SUBSTANTIAL EQUIVALENCE

Sensilight Pro by EL Global Trade Ltd. is substantially equivalent to the selected predicate devices in terms of indication for use, technology, performance, areas of usage, patient population and nature of body contact.

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

The design and components in Sensilight Pro, including the hand-held applicator (with lamp, microcontroller, fan, skin color and proximity sensors, indicator LEDs and operational button/s), are similar to the design and components found in the predicate devices (K161089 and K181734). The performance specifications (including light energy power, wavelength and pulse duration) are identical. The safety features found in the devices are the same, including the skin color sensor, skin proximity sensor, etc. These safety features in Sensilight Pro are substantially equivalent to the safety features found in the predicate devices. Any minor differences in the characteristics do not raise new safety or effectiveness concerns. Furthermore, the new Sensilight Pro 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 the predicate devices demonstrate that it is substantially equivalent to the predicate devices.