K140527
JUL 3 1 2014

EL Global Trade Ltd	Tzoran 4th St, P.O.Box 8242, Netanya 42504, Israel Tel: +972-9-7889069 Fax: +972-9-7734831
sensiLight Mini – 510K Hold Letter Respond	RD-17025 A0

510(K) SUMMARY FOR EL GLOBAL TRADE LTD.'S SENSILIGHT MINI

DATE PREPARED: JUNE 19TH, 2014

1. 510(K) OWNER NAME

EL Global Trade Ltd.
Tzoran 4th st, P.O.Box 8242, Netanya 42504, Israel.
Phone: +972-9-7889069, Fax: +972-9-7734831.

Contact person name: Dr. Shlomit Segman, QA and RA manager
Phone: +972-9-7889069, Fax: +972-9-7734831, E mail: Shlomit@elglobalt.com

2. DEVICE NAME

Common/Usual Name: Light based hair removal deices
Proprietary/Trade name: *sensiLight Mini*
Classification: EL Global Trade Ltd.'s *sensiLight* Mini 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	OHT	878.4810	General and Plastic Surgery

3. PREDICATE DEVICES

EL Global Trade Ltd.'s *sensiLight Mini* device is substantially equivalent to the following Predicate Device:

3.1 Home Skinovations Ltd.'s *Glide device*,
cleared under 510(k) number **K131870** at August 14th, 2013.

3.2 Home Skinovations Ltd.'s Silk'n Flash N Go,
cleared under 510(k) number **K103184** at November 10th, 2010.

DEVICE DESCRIPTION

The sensiLight Mini 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 sensiLight Mini device is composed of a hand held applicator and an external power supply. The spot size (treatment area) in the sensiLight Mini 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 sensiLight Mini is not properly applied (in full contact with the skin) or user skin tone is too dark/tanned, the sensiLight Mini 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.*

4. INTENDED USE

The sensiLight Mini is an over the counter devices intended for the removal of unwanted hair. The sensiLight Mini is also intended for permanent reduction in hair regrowth, 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.

5. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

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

- Wavelength of the light emitted: Defines the interaction with specific chromophores (the part of the molecule responsible for its color) such as melanin, hemoglobin and water. The sensiLight Mini device and the predicate devices utilize exactly the same wavelength (475 – 1200nm).
- Fluence/flux – defines the energy per area (e.g. joules per cm^2) for the treatment. The sensiLight Mini 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 sensiLight Mini device and the predicate devices utilize exactly the same pulse.

6. PERFORMANCE DATA

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

The sensiLight Mini device has been tested and complies with the following voluntary recognized standards:

1. IEC 60601-1:2005/EN 60601-1:2006. *Medical electric equipment-Part 1 General requirements for Basic safety and essential performance, 3rd Ed.*
2. IEC 60601-1-11:2010. *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. *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 60601-1-2:2007 *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.*
6. 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.
7. 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).
8. IEC 60601-1-6:2010, *Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance* and IEC 62366:2007 – *Medical devices – Application of usability engineering to medical devices - Collateral standard: Usability* and FDA Guidance for Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management (July18,2000) and 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.

7. NON-CLINICAL (BENCH) PERFORMANCE DATA

The objective of the Usability Study was to test the sensiLight Mini device self-selection and usability, i.e., the safe and effective device use, by potential end users, under actual use conditions.

Twenty (20) potential device end users with different Fitzpatrick skin tone and with different educational level were enrolled in the Usability Study. To strengthen the assessment that the sensiLight Mini device is intuitive and no specific training is required besides reading the Instructions for Use, self-selection was conducted in order to measure the ability of lay users to determine whether they can use the devices (based on the box labeling and instruction for use). Three participants were not enrolled to this study after self-selection screening.

The sensiLight Mini device, along with box labelling and instruction for use was provided to the participants in a simulated home use environment. The participants labeling was in the content intended for distribution. All subjects were provided with a list of tasks to complete, including applying and operating the device.

All of the 20 enrolled subjects (100%) completed all tasks successfully. The sensiLight Mini device, along with box labelling and instruction for use, can be used safely and effectively by potential end users, under actual use conditions.

8. SUBSTANTIAL EQUIVALENCE

EL Global Trade Ltd.'s *sensiLight Mini* is substantial equivalent to the predicate device selected in terms of indication for use, technology, performances, place of use, patient population and nature of body contact.

The Substantial equivalent decision was received based on the following comparison with the predicate device:

The design and components in the sensiLight Mini, 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 (K131870 and K103184). 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 the sensiLight Mini 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 sensiLight Mini 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. Usability testing was also successfully conducted.

9. CONCLUSIONS

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

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

July 31, 2014

El Global Trade Ltd.
Dr. Shlomit Segman
Quality Assurance and Regulatory Affairs Manager
Tzoran 4th Street,
P.O. Box 8242
Netanya 42504, Israel

Re: K140527
Trade/Device Name: sensiLight Mini
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
Dated: June 25, 2014
Received: July 3, 2014

Dear Dr. Segman:

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,

David Krause -S

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)*
K140527

Device Name
sensiLight Mini

Indications for Use *(Describe)*
The sensiLight Mini is an over the counter device intended for the removal of unwanted hair. The sensiLight Mini is also intended for permanent reduction in hair regrowth, 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.07.31 15:45:01 -04'00'

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