DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 8, 2016

El Global Trade Ltd
Yael Liebes-Peer
RA/ QA Manager
8 Tzoran St,
P.O. Box 8242
Netanya, 4250604 IL

Re: K161089
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 1, 2016
Received: June 6, 2016

Dear Yael Liebes-Peer:

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" (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 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 -A

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)*

K161089

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DATE PREPARED: MAY 19TH, 2016

1. 510(K) OWNER NAME

EL Global Trade Ltd.

Tzoran 8th st, P.O.Box 8242, Netanya 425068, Israel.

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

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

Phone: +972-9-7889069, Fax: +972-9-7734831, E mail: Yael@sensica.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 Devices:

3.1 EL Global Trade Ltd.'s *sensiLight Mini device,*
cleared under 510(k) number **K140527** at June 19th, 2014.

3.2 Home Skinovations Ltd.'s Silk'n *Glide device*,
cleared under 510(k) number **K141242** at May 8th, 2014.

4. DEVICE DESCRIPTION

The sensiLight Mini device is a 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.

5. INTENDED USE/ INDICATIONS FOR USE

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.

6. PERFORMANCE DATA

The sensiLight Mini device is identical in all details to the sensiLight Mini device cleared under K140527. No new performance data is reported in this submission.

7. NON-CLINICAL (BENCH) PERFORMANCE DATA

The sensiLight Mini device is identical in all details to the sensiLight Mini device cleared under K140527. No new non-clinical performance data is reported in this submission.

8. CLINICAL PERFORMANCE DATA

No new clinical performance data is reported in this submission.

9. SUBSTANTIAL EQUIVALENCE

EL Global Trade Ltd.'s sensiLight Mini is identical to the to the *sensiLight Mini* device previously cleared under K140527. The indications for use and technological characteristics of the *sensiLight Mini* device are substantially equivalent to the indications for use and technological characteristics of the previously cleared *sensiLight Mini* device (K140527) and Glide device (K141242).

Consequently, it can be concluded that the *sensiLight Mini* device is substantially equivalent to the Predicate *sensiLight Mini* and Glide devices, cleared under 510(k) K140527 and K141242, and therefore, may be legally marketed in the USA.

10. CONCLUSIONS

Based on the performance testing and comparison to predicate devices, the *sensiLight Mini* device is substantially equivalent to the previously cleared *sensiLight Mini* and Glide predicate devices.