DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 19, 2019

Elos Me & Lescolton Ltd. (Formerly Syneron
Beauty Ltd.) Ɛ 1W. .ERMGI 1. ,Sgan
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K143339
Trade/Device Name: Elos Me & Lescolton (Infinity/T009/11/12)
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: ONF
Dated: November 20, 2014
Received: November 20, 2019

Dear Ms. Janice M. Hogan:

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,

Binita S. Ashar -S

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, 2021
See PRA Statement below.

510(k) Number *(if known):* K143339

Device Name: Elos Me & Lescolton (Infinity/T009/11/12)

Indications for Use *(Describe)*

The Elos Me & Lescolton is an over-the counter device intended for the removal of unwanted hair. The Mini me is also intended for permanent reduction in hair growth following an initial treatment regimen with or without maintenance when measured at 6, 9, and 12 months.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) XX 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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510(k) SUMMARY
Elos Me & Lescolton's
Infinity

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Elos Me & Lescolton.
Kochav Yokneam Bldg.
Yokneam Industrial Zone
P.O Box 14
Yokneam Illit 20692
Israel

Phone: +1 (212) 245-2999 X 202
Facsimile: +972 (4) 9098 701

Contact Person: Bobae Kim

Date Prepared: November 20, 2019

Name of Device and Name/Address of Sponsor

Elos Me & Lescolton (Infinity/T009/11/12

Elos Me & Lescolton.
Kochav Yokneam Bldg.
Yokneam Industrial Zone
P.O Box 14
Yokneam Illit 20692
Israel

Common or Usual Name

Light based hair removal system

Classification Name

ONF- Laser surgical instrument for use in general and plastic surgery and in dermatology

Predicate Devices

Elos Me & Lescolton's (Formerly Syneron Beauty Ltd)- Mē System (K131649)

Intended Use / Indications for Use

The Elos Me & Lescoltn (Infinity/T009/11/12) is an over-the counter device intended for the removal of unwanted hair. Mini mē is also intended for permanent reduction in hair growth following an initial treatment regimen with or without maintenance when measured at 6, 9, and 12 months.

Technological Characteristics

The The Elos Me & Lescolton (Infinity/T009/11/12) consists of a handheld unit that operates with an external power supply. Identical to its predicate device, the miniaturized version also delivers Intense Pulse Light (IPL) technology (output up to 9 J/cm2) to the treatment area for removing unwanted hair.

Performance Data

Risk analysis was performed to assess the modifications to the device, and confirmed that no new risks have been raised. The following non-clinical performance testing was conducted to re-validate the modified device, against the same test methods and criteria used on the predicate device cleared in K131469 that includes:

- Electrical safety
- Electromagnetic compatibility testing
- Software verification and validation testing
- System verification and validation testing

In all instances, the The Elos Me & Lescolton (Infinity/T009/11/12) device functioned as intended.

Substantial Equivalence

The The Elos Me & Lescolton (Infinity/T009/11/12) is as safe and effective as the predicate device, the mē System (K131649). The device uses the same technology and wavelength of light and has the same intended and indications for use and principle of operation as the predicate device. The main safety features that include the skin contact sensor and cooling fan in the predicate device are also preserved in the The Elos Me & Lescolton (Infinity/T009/11/12). Furthermore, the device delivers energy within the same limits as the predicate device including the rate and duration of each pulse emission and therefore no new questions of efficacy are raised in the modified device. Any minor differences in the dimensions and hardware of the The Elos Me & Lescolton (Infinity/T009/11/12) compared to its predicate device do not raise new issues of safety or effectiveness in the modified device. Verification and validation testing demonstrated that the The Elos Me & Lescolton (Infinity/T009/11/12) is as safe and effective as the mē System (K131649). There were no new hazards identified as a result of these minor modifications and therefore the The Elos Me & Lescolton (Infinity/T009/11/12) System is substantially equivalent.