 K123845

510(k) SUMMARY

JAN 10 2013

Syneron Beauty Ltd.'s mē

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

Syneron Beauty Ltd.
Kochav Yokneam Bldg.
Yokneam Industrial Zone
P.O Box 14
Yokneam Illit 20692
Israel

Phone: +972 (4) 9098 700
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Contact Person: Omri Hayet

Date Prepared: December 12, 2012

Name of Device and Name/Address of Sponsor

mē

Syneron Beauty Ltd.
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

mē (K121598)

Intended Use / Indications for Use

The mē is an over-the counter device intended for the removal of unwanted hair.

Technological Characteristics

The mē device is a small over-the-counter, compact system comprised of a base unit assembly with power supply, and connected, via cable, to a handheld applicator with an air-cooling system. The device incorporates Intense Pulse Light (IPL) technology (output 2-4 J/cm^2), like other OTC devices for hair removal. It also uses low RF energy (output 0.4-0.8 J/cm^2) delivered through the RF electrodes. The RF signal serves primarily as a safety means to ensure skin contact before the IPL pulse is emitted. The only changes made in the current version compared to the previously cleared device relate to a minor electronics and software update, and ergonomic enhancements to the applicator and base unit control panel. All key characteristics, including energy source (IPL and radiofrequency), the output of energy, the settings and pulse duration remain unchanged.

Performance Data

The following non-clinical performance testing was conducted to re-validate the updated version of the mē device compared against the same test methods and criteria used on the predicate device cleared in K121598.

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

In all instances, the modified mē device functioned as intended.

Substantial Equivalence

The updated model of the mē device is as safe and effective as the mē (K121598). The modified mē device has the same intended uses and same indications as the predicate. The technological characteristics and principles of operation are also very similar to its predicate device. The minor differences in aesthetics, software and electronics between the modified device and its predicate device do not raise any new types of safety or effectiveness questions, as confirmed by software verification and validation, electrical safety, and electromagnetic compatibility/interference testing. No changes in materials resulted from the minor device modifications. Performance data demonstrate that the modified mē device performs as expected. Thus, the modified mē device is substantially equivalent.

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

Syneron Beauty, Limited
% Hogan Lovells US, LLP
Ms. Janice M. Hogan
Regulatory Counsel
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Letter dated: January 10, 2013

Re: K123845
Trade/Device Name: mē
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: December 13, 2012
Received: December 13, 2012

Dear Ms. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123845

Device Name: me

Indications For Use: The me is an over-the-counter device intended for the removal of unwanted hair.

Prescription Use _____ AND/OR Over-The-Counter Use _X_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Neil R Ogden
2013.01.10 10:55:14 -05'00'

(Division Sign-Off)
Division of Surgical Devices
510(k) Number _____