510(k) SUMMARY

OCT 12 2012

Syneron Medical Ltd.'s mē Device

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

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Date Prepared: May 30, 2012

Name of Device

mē

Common or Usual Name

Light based hair removal system

Classification Name

GEX

Predicate Devices

Home Skinovations Ltd.'s Silk'n Flash N'Go (K082298; K103184)

Shaser IPL Hair Removal System (K103560)

Spectragenics, Inc.'s Tria Laser Hair Removal System (K090820)

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.

Performance Data

The following nonclinical performance testing was conducted to support the substantial equivalence of the **mē**:

- electrical safety
- electromagnetic compatibility testing
- optical radiation safety
- device integrity testing (packaging/transport)
- biocompatibility testing for cytotoxicity, irritation and skin sensitization
- software verification and validation testing, and
- testing to characterize both the external device temperature at the skin interface and the resultant temperature increase in the skin.

The following clinical testing was conducted to support the safety and efficacy of the mē:

- Efficacy and safety study under the intended conditions of use:
  - An 87-patient multi-center (4 sites) clinical study to demonstrate effective use of the device, in a simulated home-use setting.
  - The study evaluated the efficacy of the mē hair removal device at 1 and 3 months after the final basic (7th) treatment and compared the extent of hair removal with 3 additional monthly maintenance treatments vs. without the 3 additional monthly maintenance treatments.
  - Significant hair clearance was achieved for all skin types groups (skin type I-VI), even without the monthly maintenance treatments.

- Dedicated study, under extreme conditions of overuse, to confirm safety:
  - A 37-patient clinical study to establish safety with a treatment protocol that simulated frequent (over) use of the device.
  - The study included participants with Fitzpatrick skin types (II-VI); each patient received treatment on at least 2 anatomical sites, each of which was treated

bilaterally, for a total of at least 4 sites per subject. The results showed no adverse events even under overuse conditions.

- Label comprehension and usability study to test consumers' ability to understand the instructions for use including contraindications and to evaluate their ability to use the device safety in simulated home use conditions.
    - 63 participated in the label comprehension study and 46 subjects participated in the usability testing. These included low literacy participants.

The results confirmed adequate label comprehension and correct device use in an OTC environment.

All of these tests confirmed that the **mē** performs as intended.

Substantial Equivalence

The **mē** is substantially equivalent to the Home Skinovations Ltd. Silk'n Flash N'Go (K082298; K103184), the Shaser IPL System (K103560), and the Spectragenics, Inc. Tria Laser Hair Removal System (K090820).

The **mē** has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the **mē** and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that these minor differences do not adversely impact performance of the device for its intended use. Thus, the **mē** is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

OCT 12 2012

Re: K121598
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: September 24, 2012
Received: September 24, 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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K121598

Device Name: mē

Indications for Use:

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

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121598