K131649

DEC 11 2013

510(k) SUMMARY

Syneron Beauty Ltd.'s mē

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

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Date Prepared: December 11, 2013

Name of Device and Name/Address of Sponsor

mē

Syneron Beauty Ltd.
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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, Class II, 21 CFR 878.4810

Predicate Devices

Syneron Beauty Ltd.'s mē (K123845; K121598)
Shaser Inc.'s IPL Hair Removal System (K120080; K103560)
Tria Beauty, Inc's Tria Laser Hair Removal System (K090820; K120737)

Intended Use / Indications for Use

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

Device Description

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. The purpose of the light is to heat the root where the hair grows.

Technological Characteristics

There are no technological differences between the mē device presented in this submission and the previously cleared versions of the device (K123845, K121598). The device incorporates Intense Pulse Light (IPL) technology (output 2-4 J/cm^2), like other OTC devices for hair removal.

The nonclinical evaluations of the mē device were performed in support of clearance of the predicate mē devices, and the information regarding sterilization, shelf life, biocompatibility, and electromagnetic compatibility and electrical safety remain unchanged.

Clinical Performance Data

In a medically supervised clinical study, the mē was effective in the removal of unwanted hair, when used as directed. 87 healthy, dark haired participants of all skin types (I-VI) and between the ages of 18 to 65 years old, who were willing to refrain from any type of hair removal methods beyond shaving during the study duration, were enrolled. A treatment area (5x5 cm^2) in the underarms, arms and legs were treated once a week for 7 treatments, over a period of 6 weeks, and were evaluated at 3 months after treatment also known as the "3-Month Group". Thereafter, 58 (54 females and 4 males with an average age of 34 years old) of these participants continued in long term clinical studies to evaluate permanent hair reduction at 6, 9 and 12 months with and without monthly maintenance treatments after the initial 7 treatments had been completed.
Table 1 presents the study data for subjects that did not receive monthly maintenance treatments after the initial regimen of 7 treatments ("No Maintenance" group), and Table 2 presents the data for subjects who received monthly treatment after the initial treatment period ("Initial and Maintenance Treatment" group). 72% of subjects were of light skin tone (Skin type I-IV) while the remainder were of darker skin tone (Skin Type V and VI). The "6-month Group" consisted of 40 participants. Each participant had a non-maintenance side and a maintenance side per body area (arms, legs and axilla) and monthly treatments were performed only on the maintenance side. Similarly, the "9-Month Group" consisted of 26 subjects and lastly the "12-Month Group" consisted of 44 subjects.

The end point for the long term clinical studies was the overall hair reduction achieved at 6, 9 and 12 months following a basic treatment regimen (7 weekly treatments) as measured by two independent evaluators through hair count on images taken from the treatment area that were subsequently averaged. These images were taken just before the first treatment and at subsequent follow ups within the study period of up to 1 year. The effects of performing monthly maintenance following the Basic Treatment regimen of 7 weekly treatments were evaluated in participants of the various study groups at 6, 9 and 12 months from the start of the study and are summarized in the table below. A subject was considered a success if all treated body parts achieved greater than 30% hair reduction at that time point. A body site is considered a success if the treated site achieved greater than 30% hair reduction at that time point.

There were no serious adverse events observed during the entire course of all study evaluations conducted and any minor transient effects such as skin irritation or redness were documented by medical personnel and are described below.

*Table 1 below represents subjects who were evaluated in at least one follow up time point. Non maintenance body sites received only the initial (basic) treatment (7 weekly treatments) with the mē device and no additional treatment during follow-up assessments at up to 12 months after end of basic treatment.
Note: There were 40 participants at the 6 month visit, 26 participants at the 9 month visit and 44 participants at the 12 month visit. A total of 58 participants were evaluated in at least one follow up time point 6, 9 or 12 months. Subjects were evaluated at 2, 3, or all follow up time points.

Table 1: Hair Reduction Data with Initial Treatment Regimen (No Maintenance*) (Return for Follow Up at Variable Time Points 6 or 9 or 12 Months)

	Average Results
Initial (Basic) Treatment (7 weekly treatments)	54% reduction observed in 87 participants (143 sites)
3-Month Group	44% reduction observed in 87 participants (139 sites)
	Long Term (≥6 months) Follow-Up
6-Month Group	48% reduction (40 participants, 65 sites)
9-Month Group	45% reduction (26 participants, 44 sites)
12-Month Group	37% reduction (44 participants, 72 sites)
% subjects met success (>30% hair reduction) on all body sites at 12 months post-treatment Subject Success is defined as greater than 30% hair reduction at all treatment sites at 12 months.	45% success observed in the 44 subjects with long-term follow-up at 12 months
% body sites met success (>30% hair reduction) at 12 months post-treatment Body site success is defined as greater than 30% hair reduction on arm or leg or axilla at 12 months.	54% success observed in the 72 sites with long-term follow-up at 12 months

**Table 2 represents body sites where maintenance was performed throughout the study. Like Table 1 these subjects were evaluated in at least one follow up time point. For maintenance body sites, the subjects were assigned to perform maintenance treatments monthly after completing the initial (basic) treatment regimen.
Note: There were 40 participants at the 6 month visit, 26 participants at the 9 month visit and 44 participants at the 12 month visit. A total of 58 participants were evaluated in at least one follow up time point 6, 9 or 12 months. Subjects were evaluated at 2, 3, or all follow up time points.

Table 2: Hair Reduction Data with Initial and Maintenance Treatment (Return for Follow Up at Variable Time Points 6 or 9 or 12 Months)**

	Average Results
Initial (Basic) Treatment (7 weekly treatments)	57% reduction observed in 87 participants (143 sites)
3-Month Group	58% reduction observed in 87 participants (142 sites)
	Long Term (≥6 months) Follow-Up
6-Month Group	55% reduction (40 participants, 69 sites)
9-Month Group	56% reduction (26 participants, 46 sites)
12-Month Group	52% reduction (44 participants, 75 sites)
% subjects met success (>30% hair reduction) on all body sites at 12 months post-treatment Subject Success is defined as greater than 30% hair reduction at all treatment sites at 12 months.	59% success observed in the 44 subjects with long-term follow-up at 12 months
% body sites met success (>30% hair reduction) at 12 months post-treatment Body site success is defined as greater than 30% hair reduction on arm or leg or axilla at 12 months.	72% success observed in the 75 sites with long-term follow-up at 12 months

Tables 3 and 4 show data from the 21 of the 87 participants who completed non-maintenance (Table 3) and monthly maintenance (Table 4) treatments for up to 1 year continuously following their initial weekly basic treatments and returned for follow-up at 6, 9 and 12 months. As shown in the tables below, this subgroup of participants had slightly higher hair reduction at 12 months. Unlike Tables 1 and 2, the subjects in Tables 3 and 4 were evaluated at all follow up time points of 6, 9, and 12 months.

Table 3: Hair Reduction Data with Initial Treatment (No Maintenance*) for Participants Returned for Follow Up at 6, 9 and 12 months

	Average Results
Basic Treatment (7 weekly treatments)	54% reduction observed in 87 participants (143 body sites)
3 Months after Initial Treatment	44% reduction observed in 87 participants (139 body sites)

	Long Term (≥6 months) Follow-up
6 Months after Initial Treatment	44% reduction observed in 21 participants (37 body sites)
9 Months after Initial Treatment	45% reduction observed in 21 participants (37 body sites)
12 Months after Initial Treatment	42% reduction observed in 21 participants (37 body sites)
% subjects met success (>30% hair reduction) on all body sites at 12 months post-treatment Subject Success is defined as greater than 30% hair reduction at all treatment sites at 12 months.	52% success observed in the 21 subjects with long-term follow-ups to 12 months
% body sites met success (>30% hair reduction) at 12 months post-treatment Body site success is defined as greater than 30% hair reduction on arm or leg or axilla at 12 months.	68% success observed in the 37 sites with long-term follow-up at 12 months

* Non maintenance body sites received only the initial (basic) treatment (7 weekly treatments) with the mē device and no additional treatment during follow-up assessments at up to 12 months after end of basic treatment.

Table 4: Hair Reduction Data with Initial and Maintenance Treatment for Participants Returned for Follow Up at 6, 9 and 12 months**

	Average Results
Basic Treatment (7 weekly treatments)	57% reduction observed in 87 participants (143 body sites)
3 Months after Initial Treatment	58% reduction observed in 87 participants (142 body sites)
	Long Term (≥6 months) Follow-up
6 Months after Initial Treatment	55% reduction observed in 21 participants (40 body sites)
9 Months after Initial Treatment	59% reduction observed in 21 participants (40 body sites)
12 Months after Initial Treatment	60% reduction observed in 21 participants (40 body sites)
% subjects met success (>30% hair reduction) on all body sites at 12 months post-treatment Subject Success is defined as greater than 30% hair reduction at all treatment sites at 12 months.	62% success observed in the 21 subjects with long-term follow-ups to 12 months
% body sites met success (>30% hair reduction) at 12 months post-treatment Body site success is defined as greater than 30% hair reduction on arm or leg or axilla at 12	80% success observed in the 40 sites with long-term follow-up at 12 months

months.	

**For maintenance body sites, the subjects were assigned to perform maintenance treatments monthly after completing the initial (basic) treatment regimen.

Actual results will vary from person to person and depending on body site being treated (arms, legs, or underarms). Hair re-growth may fluctuate (increase or decrease) over time, depending on the person, body area and whether the instructions were followed correctly. While permanent reduction of hair results can be achieved without monthly maintenance, it is recommended that user's perform monthly treatments following their basic treatments.

As noted above, there were no serious adverse events in the clinical study. In the clinical study, the majority (85%) of participants did not experience side effects with treatment. The most common side effect is redness after treatment that disappears within several hours without medical treatment. In addition, folliculitis may be observed in some cases.

The user may feel warmth, tingling, or itching. It is expected that the user may feel up to a moderate level of pain. If the pain is severe/intense or the pain persists for more than 24 hours after a treatment, consultation with a physician is recommended.

In the clinical study, the following side effects of treatment were reported:

Anticipated Effects on Skin Appearance	**Number of Reports**	**Incidence (%) / of 3,122 treatments**	**% Subjects (n/102)***
Redness	20	0.6%	4% (4/102)
Pruritis/itching	2	0.06%	1% (1/102)
Edema	2	0.06%	1% (1/102)
Inflammation	2	0.06%	1% (1/102)
Acne	2	0.06%	2% (2/102)
Total Anticipated	***28***	***0.9%***	***9% (9/102)****
Device-related Adverse Events			
Infection	0	0%	0% (0/87)
Blister	2	0.06%	1% (1/102)
Hyper/hypopigmentation	0	0%	0% (0/87)
Scarring	0	0%	0% (0/87)
Severe pain	11	0.3%	2% (5/102)
Total Adverse Events	***13***	***0.4%***	***6% (6/102)***
Overall anticipated effects + adverse events	***41***	***1%***	***15% (15/102)***

* Safety evaluations were reported for a total of 102 subjects including the 87 subjects included in the efficacy data for up to 3 months post-treatment and an additional 15 subjects included in the long-term studies for >6 months follow-up after treatment.

Substantial Equivalence

The mē is substantially equivalent to the Company's own previously cleared mē device (K123845; K121598), Shaser's IPL System (K120080; K103560), and Tria Beauty, Inc's Tria Laser Hair Removal System (K090820; K120737).

The mē has the same intended use and similar indications for use, technological characteristics, and principles of operation as its predicate devices. As noted above, the only principal change implemented in this submission compared to the previously cleared device version is to expand the indications for use of the device to include permanent hair reduction, based on longer-term clinical data through 12 months. Clinical data substantiates permanent hair reduction of at least 30% measured at 12 months post-treatment compared to baseline. This indication encompasses the same long term data (12 months) as other previously cleared predicates devices such as the Shaser's IPL System (K120080; K103560) and the Tria Laser Hair Removal System (K090820; K120737). No changes to the device specifications were required to support the expanded indications for use. Thus, there are no technological differences between the mē device presented in this submission and the previously cleared versions of the device (K123845, K121598). Clinical data supports expansion of the indications for use to include permanent hair reduction. Thus, the mē is substantially equivalent.

Conclusion

Therefore, the nonclinical and clinical evaluations of the mē device demonstrate that the device performs as intended, and is substantially equivalent to 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 20993-002

December 11, 2013

Syneron Beauty Ltd.
c/o Hogan Lovells US LLP
Janice M. Hogan
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K131649
Trade/Device Name: mē Hair Removal System
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 07, 2013
Received: November 07, 2013

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,

Binita S. Ashar -S
2013.12.11 17:14:24 -05'00'

Binita Ashar, MD, MBA, FACS
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): K131649

Device Name: Syneron me

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

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden -S
2013.12.11 15:00:46 -05'00'

(Division Sign-Off) for BSA

Division of Surgical Devices

510(k) Number K131649