SUMMARY OF SAFETY AND EFFECTIVENESS

K131870
(Premarket Notification [510(k)] Number)

Applicant Name:

Company Name: Home Skinovations Ltd.
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Tel: +972(4)9097470
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AUG 1 4 2013

Contact Person:

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Date Prepared: June 18, 2013

Trade Name: Glide Device

Classification Name: CFR Classification section 878.4810; (Product code OHT)

Classification: Class II Medical Device

Predicate Device:

The Glide device is substantially equivalent to the previously cleared, Silk'n Flash N Go device, also manufactured by Home Skinovations Ltd.:

Device	**Manufacturer**	**510(k) No.**
Silk'n Flash N Go	**Home Skinovations Ltd.**	**K103184**

Device Description:
The Glide 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 Glide device is composed of a hand held applicator. The device contains 6 LEDs indicated 5 different energy levels and other device functions. The spot size in the Glide device is 2.7cm^2. The device contains a lamp, a temperature sensor, a skin proximity sensor and a skin color sensor to detect appropriate skin tones. The skin sensor scans darker skin tones and will not pulse if the skin tone is not suitable for treatment.

Intended Use/Indication for Use:
The Glide™ device is an over the counter device intended for the removal of unwanted hair. The Glide™ device is also intended for permanent reduction in hair regrowth, defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

Performance Standards:
The Glide device has been tested and complies with the following voluntary recognized standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995
- IEC 60601-1-2 (2007), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests
- EN 62471: 2008 Photobiological safety of lamps and lamp systems
- EN 60601-2-57: 2011 Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use.
- Software Validation according to the IEC 60601-1-4 standard and the FDA Guidance for the Content of PreMarket Submissions for Software Contained in Medical Devices.

Non-Clinical (Bench) Performance Data:
The objective of the Usability Study was to test the Glide device usability, i.e., the safe and effective device use, by potential end users, under actual use conditions.

Twenty (20) potential device end users were enrolled in the Usability Study. The Glide device, in its original packaging, along with the user manual and QuickStart guide was provided to the patient in a simulated home use environment. The patient labeling was in the format intended for distribution. All subjects were provided with a pre-test and post-test questionnaire and a list of tasks to complete, including applying and operating the device.

All of the 20 enrolled subjects (100%) completed all tasks successfully. The Glide device, in its

original packaging, along with the user manual and QuickStart guide, can be used safely and effectively by potential end users, under actual use conditions.

Clinical Performance Data:
Not applicable.

Substantial Equivalence:
The indications for use and technological characteristics of the Glide device are substantially equivalent to the indications for use and technological characteristics of the Silk'n Flash N Go device.

The design and components in the Glide device, including the hand piece applicator (with 12V regulator, lamp, microcontroller, fan, temperature sensor, skin color sensor, skin proximity sensor, indicator LEDs and operational button/s) are similar to the design and components found in the predicate Silk'n Flash N Go device, although in the predicate device these components are found in either the hand piece applicator or the base unit and in the Glide device all components are in the hand piece applicator. The performance specifications (including light energy power, wavelength and pulse duration) in all the devices are identical. The safety features found in all the devices are the same, including the system self-check, temperature sensor, skin color sensor, skin proximity sensor, etc. These safety features in the Glide device are substantially equivalent to the safety features found in the predicate device. Any minor differences in the technological characteristics do not raise new safety or effectiveness concerns. Furthermore, the new Glide device underwent performance testing, including software validation testing and electrical and mechanical safety testing according to IEC 60601-1 and electromagnetic compatibility testing according to IEC 60601-1-2 (provided in Section 12). Usability testing was also conducted due to the design changes in the operational buttons and indicator LEDs in the Glide device and the results are presented in Section 12, as well. These performance tests demonstrate that the minor differences in the device software and design meet the system requirements and do not raise new safety or effectiveness concerns.

Consequently, it can be concluded that the Glide device is substantially equivalent to the predicate Silk'n Flash N Go device, cleared under 510(k) K103184 and therefore, may be legally marketed in the USA.

Conclusions:
Based on the performance testing and comparison to the predicate device, the Glide device is substantially equivalent to the Silk'n Flash N Go predicate device.

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

Regulatory Affairs Consulting Ltd.
% Ahava Stein
20 Hata'as Street., Suite 102
Kfar Saba, Israel 44425

August 14, 2013

Re: K131870
Trade/Device Name: Glide Device
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: July 16, 2013
Received: August 8, 2013

Dear Ms. Stein:

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 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. 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,

FOR

Peter D. Rumm -S

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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K131870

Device Name: Glide Device

Intended Use Statement:

The Glide™ device is an over the counter device intended for the removal of unwanted hair. The Glide™ device is also intended for permanent reduction in hair regrowth, defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

Prescription Use _____ OR Over-The-Counter Use √
(Per 21 C.F.R. 801 Subpart D) (Optional Format Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2013.08.13 15:28:14 -04'00'

(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number K131870