K103184

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Home Skinovations Ltd.

Silk'n Flash N Go

NOV 1 0 2010

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter's information

Name:	Home Skinovations Ltd.
Address:	Apolo building, POB 533, Yokneam 20692, Israel
Contact:	Dr. Amir Waldman VP Regulatory Affairs

Device information

Trade/Proprietary name:	Silk'n Flash N Go
Common/Usual name:	Light based hair removal device
Classification name:	Laser surgical instrument for use in general and plastic surgery and in dermatology (21CRF §878.4810)
Product code:	GEX

Predicate devices

- Flash N Go (K082298), by Home Skinovations Ltd.
- TRIA Laser Hair Removal System (K090820),by Tria Beauty, Inc.
- EpiLight and PhotoDerm HR (K991935), by ESC Medical system Inc.

Intended use:

The Flash N Go device is an over the counter device intended for the removal of unwanted hair. Flash N Go is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime.

Device Description:

The Flash N Go hair removal system is a pulsed light system composed of a base unit and hand held applicator.

Performance data:

The device complies with the following U.S. Food and Drug Administration performance standards: 21CRF § 1040.10 & 1040.11. Clinical data was collected in a prospective multisite clinical study.

Substantial Equivalence:

The Flash N Go system is substantial equivalent to its predicate devices. The data in this 510k submission demonstrate that the Flash N Go system is identical to the cleared Flash N' Go, and shares the same intended use as other predicate devices. Therefore is substantial equivalent to its predicate devices. Details are provided in Substantial equivalent section of this submission.

Based upon an analysis of the overall performance characteristic for the device, Home Skinovations Ltd. believes that no significant differences exit. Therefore the Silk'n Flash N Go should raise no new issues of safety or effectiveness.

October 21, 2010

Date

Dr. Amir Waldman,
VP Regulatory Affairs
Home Skinovations Ltd.

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

Home Skinovations Ltd.
% Dr. Amir Waldman
Vice President, Regulatory Affairs
Apolo Building, P.O. Box 533
Yokneam 20692, Israel

NOV 10 2010

Re: K103184
Trade/Device Name: Silk'n Flash N Go
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: October 21, 2010
Received: October 29, 2010

Dear Dr. Waldman:

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

510(k) Number (if known) K103184

Device Name Flash N Go

Indications For Use: NOV 10 2010

Flash N Go is an over the counter device intended for the removal of unwanted hair.

Flash N Go is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over The Counter Use_X_
(Per 21 CFR 801.109)

Neil R. Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

(Optional Format 1-2-96)

510(k) Number K103184

FDA קישור לאתר – Flash &Go

http://www.accessdata.fda.gov/cdrh_docs/pdf10/K103184.pdf