

MAY 18 2011

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter Name: SHASER Inc.
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Contact Person: Daniel L. Roth
Phone Number: (781)995-2246
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Date Prepared: November, 2010
Device Trade Name: Shaser IPL Hair Removal System
Device Common Name: Light-based Hair Removal System
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology, product code GEX
Predicate device: Home Skinovations Flash N' Go, K082298
Tria Beauty Tria Laser Hair Removal System, K090820
Reason for submission: Not previously marketed in the USA

Device Description:

The SHASER IPL Hair Removal System is a personal, light-based, hair reduction system intended to be sold over-the-counter directly to the end user. The device provides hair reduction using Intense Pulsed Light (IPL) technology.

The SHASER IPL Hair Removal System consists of a powered base unit and a tethered handpiece from which the IPL flashes are delivered to the patient's skin. The system will be sold with light cartridges, cleaning cloth, and user's manual.

Intended Use:

The SHASER IPL Hair Removal System is an over the counter device intended for removal of unwanted hair.

Performance Data

The device complies with the following U.S. Food and Drug Administration performance standards: 21CFR § 1040.10 & 1040.11. A clinical trial was conducted to demonstrate the safety and effectiveness of the SHASER IPL Hair Removal System for over-the-counter use for hair removal. In a clinical trial, 111 test sites including arm, leg, chest, abdomen, bikini line and underarms were treated 3 times at 2 week intervals on a population of approximately 50% female and 50% male subjects from diverse demographical sub-groups. Hair counts were taken before treatment and 3 and 6 months following the final treatment. The results showed an average reduction of 37% and 48% at each respective end point.

Substantial Equivalence**Technological Characteristics and Comparison to Predicate Device(s):**

The SHASER IPL Hair Removal System is substantially equivalent to the Home Skinovations Flash N' Go, K082298, and the Tria Beauty Tria Laser Hair Removal System, K090820.

The SHASER IPL Hair Removal System has the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate devices. Any minor differences between the SHASER IPL Hair Removal System and its predicate devices raise no new questions of safety or effectiveness nor change the device's intended therapeutic effect in comparison to its predicates. Performance data demonstrate that SHASER IPL Hair Removal System is as safe and effective as its predicate devices for the stated indications. Thus, SHASER IPL Hair Removal System is substantially equivalent.



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

Shaser, Inc.
% The CRO Group, Inc.
Mr. Glen Emelock
32 Harrison Street
Melrose, Massachusetts 02176

MAY 18 2011

Re: K103560

Trade/Device Name: Shaser IPL 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: May 11, 2011
Received: May 16, 2011

Dear Mr. Emelock:

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.

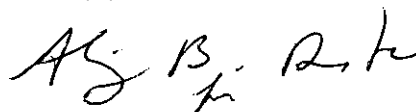
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

510(k) Number: K103560

Device Name: SHASER IPL Hair Removal System

Indications For Use:

The SHASER IPL Hair Removal System is an over the counter device intended for removal of unwanted hair.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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