SEP 13 2012

510(k) SUMMARY

TRIA Beauty's TRIA Laser Hair Removal System

K120737

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

TRIA Beauty, Inc.
4160 Dublin Blvd., Suite 200
Dublin, CA 94568

Phone: 925-452-2539
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Contact Person

Lisa Parr, Pharm.D.

Date Prepared

September 7, 2012

Name of Device and Name/Address of Sponsor

TRIA Laser Hair Removal System

TRIA Beauty, Inc.
4160 Dublin Blvd., Suite 200
Dublin, CA 94568

Common or Usual Name

Pulsed Diode Laser

Classification Name

Laser Instrument, Surgical, Powered
Regulation Number: 21 C.F.R.§ 878.4810
Product Code: GEX

Predicate Devices

TRIA Laser Hair Removal System (K090820)

Intended Use / Indications for Use

TRIA is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. TRIA is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime. Permanent hair reduction is defined as long term, stable reduction in the number of hairs regrowing when measured out to 6, 9, and 12 months after the completion of the treatment regimen.

Technological Characteristics

TRIA is a semiconductor diode laser system that delivers infrared light at a wavelength of nominally 800 nm +/- 20%.

Performance Data

Clinical trials have been conducted to demonstrate the safety and efficacy of TRIA for over-the-counter use for hair removal sustained with periodic treatments and for permanent reduction in hair regrowth.

Substantial Equivalence

The TRIA used in the clinical study is the previously cleared TRIA. The TRIA has the same intended uses and similar indications, technological characteristics, and principles of operation as the previously cleared TRIA. Performance data demonstrate that the TRIA is as safe and effective as its predicate. Thus, the TRIA 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

SEP 13 2012

TRIA Beauty, Incorporated
% Hogan and Lovells US, LLP
Mr. Jonathan Kahan
Regulatory Counsel
Columbia Square
555 13th Street, Northwest
Washington, District of Columbia 20004

Re: K120737
Trade/Device Name: TRIA Laser Hair Removal System (TRIA)
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: GEX
Dated: August 28, 2012
Received: August 28, 2012

Dear Mr. Kahan:

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.

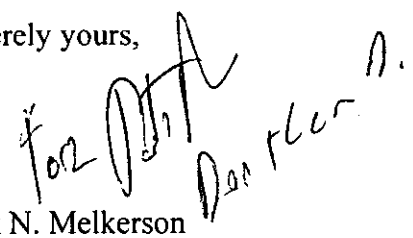
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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: K120737

Device Name: TRIA Laser Hair Removal System (TRIA)

Indications for Use:

TRIA is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. TRIA is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime. Permanent hair reduction is defined as long term, stable reduction in the number of hairs regrowing when measured out to 6, 9, and 12 months after the completion of the treatment regimen.

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)

for mxn

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

510(k) Number K120737