K130459

510(k) SUMMARY

Tria Beauty's Tria FAN System

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

Tria Beauty, Inc.
4160 Dublin Blvd, Ste 200
Dublin, CA 94568
Phone: 925-452-2500
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Contact Person: Tobin Island, Ph.D.
Date Prepared: September 12, 2013

Name of Device and Name/Address of Sponsor

Tria FAN System
Tria Beauty, Inc.
4160 Dublin Blvd, Ste 200
Dublin, CA 94568

Common or Usual Name

OCT 25 2013

Diode Laser

Classification Name

Laser Instrument, Surgical, Powered
Regulation Number: 21 CFR§878.4810
Product Code: ONG

Predicate Devices

Palomar LOI System (K090525)
Cynosure Iluminage Diode Laser (K111454)
Cynosure Affirm Laser Family (K080006; K101601)
Solta Fraxel Re:Fine Laser (K091420; K060310; K063808; K062303; K070284; K050841; K042319; K040617; K031795)

Intended Use / Indications for Use

Tria FAN is indicated for the treatment of periorbital wrinkles, which may result in smoother appearing skin in the treated area.

Technological Characteristics

The Tria FAN System is a semiconductor diode laser system that delivers infrared light at a wavelength of 1450 nm ± 50 nm.

Performance Data

Performance data was submitted with this 510(k) notification to support the determination of substantial equivalence for the Tria FAN System relative to predicate devices.

Performance Testing (Non-Clinical):

Performance testing was conducted to demonstrate that the Tria FAN System performs according to specifications and functions as intended.

Animal:

A GLP compliant histology study was conducted. Hairless guinea pigs were treated with the Tria FAN System and tissue sampling occurred immediately, 5 days, and 14 days post-treatment. The tissue response was found to be equivalent to the predicate non-ablative fractional devices.

Clinical:

A 60-subject, prospective, open-label safety and effectiveness study was conducted to evaluate the Tria FAN System for the treatment of periorbital wrinkles. The Tria FAN System was found to be as safe and effective as the predicate non-ablative fractional devices.

Substantial Equivalence

The Tria FAN System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Tria FAN System and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Tria FAN System is as safe and effective as the predicate devices. Thus, the Tria FAN System is substantially equivalent.

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

October 25, 2013

Tria Beauty, Incorporated
% Mr. Tobin Island, Ph.D.
4160 Dublin Boulevard, Suite 200
Dublin, California 94568

Re: K130459
Trade/Device Name: Tria Fan
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: ONG
Dated: September 23, 2013
Received: September 23, 2013

Dear Mr. Island:

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,

Mark N. Melkerson -S

Mark N. Melkerson
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): K130459

Device Name: Tria Fan

Indications For Use:

Tria FAN is indicated for the treatment of periorbital wrinkles, which may result in smoother appearing skin in the treated area.

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 Center for Devices and Radiological Health (CDRH)

Neil R Ogden
2013.10.25 13:17:42 -04'00'
(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number K130459