K090312

510(k) SUMMARY

ATS-1 OTC

JAN - 5 2010

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

TRIA Beauty, Inc.
5880 W. Las Positas Blvd., Suite 52
Pleasanton, CA 94588-8552
Phone: 925-701-2549
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Contact Person: Tobin C. Island, Ph.D.
Date Prepared: February 5, 2009

Name of Device and Name/Address of Sponsor

TRIA Acne Treatment System (ATS-1 OTC)
TRIA Beauty, Inc.
5880 W. Las Positas Blvd., Suite 52
Pleasanton, CA 94588-8552

Common or Usual Name

Light Emitting Diode Therapy System

Classification Name

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

Predicate Devices

ATS-1 by TRIA Beauty, Inc. (formerly SpectraGenics, Inc.) (K060567)
ThermaClear by Therative, Inc. (K060653)
Zeno by Tyrell, Inc. (K043377)
Tanda by Pharos Life Corporation (K080591)

Intended Use / Indications for Use

The ATS-1 OTC is generally indicated to treat dermatological conditions and specifically indicated to treat mild to moderate inflammatory acne vulgaris. It is intended for over-the-counter use.

Technological Characteristics

The ATS-1 OTC is a handheld, electrically powered device that uses LEDs (light emitting diodes) to produce therapeutic blue light.

Performance Data

TRIA Beauty claims that the ATS-1 OTC performance data is substantially equivalent to the predicate devices, including and especially the company's previously cleared ATS-1 (K060567). Performance and consumer usability data is submitted with this 510(k) notification.

Substantial Equivalence

The ATS-1 OTC has substantially the same intended use, indications for use, technological parameters, and mechanism of action as the predicate device(s). Furthermore, the performance and consumer usability data demonstrates that any technological differences or changes in labeling do not raise new questions of safety or efficacy or alter the device's intended therapeutic effect in comparison to the predicates. Therefore, the ATS-1 OTC is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN - 5 2010

TRIA Beauty, Inc.
% Hogan and Hartson LLP
Mr. Jonathan S. Kahan
Columbia Square
555 13th Street, N.W.
Washington, District of Columbia 20004

Re: K090312
Trade/Device Name: TRIA Acne Treatment System (ATS-1 OTC)
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: December 09, 2009
Received: December 09, 2009

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.

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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

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 (if known):_____

Device Name: ATS-1 OTC

Indications for Use:

The TRIA Beauty ATS-1 OTC is generally indicated to treat dermatological conditions and specifically indicated to treat mild to moderate inflammatory acne vulgaris.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K090312