



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 15, 2016

Tria Beauty, Inc.
% Mr. Jonathan Kahan
Regulatory Counsel
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, District of Columbia 20004

Re: K160821

Trade/Device Name: Tria Sapphire
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: OLP
Dated: March 24, 2016
Received: March 24, 2016

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 contact the Division of Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K160821

Device Name

Tria Sapphire

Indications for Use (Describe)

The Tria Sapphire is indicated for the treatment of mild to moderate inflammatory acne.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

510(k) SUMMARY

Tria Beauty's Tria Sapphire

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
Facsimile: 925-452-2597
Contact Person: Heather Tanner
Date Prepared: March 23, 2016

Name of Device and Name/Address of Sponsor

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

Common or Usual Name

Light Therapy System

Classification Name

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

Predicate Devices

Tria Beauty, Inc., ATS-1 OTC (K090312)

Intended Use / Indications for Use

The Tria Sapphire is indicated for the treatment of mild to moderate inflammatory acne. It is intended for over-the-counter use.

Technological Characteristics

The Tria Sapphire is a handheld, electrically powered device that uses LEDs (light emitting diodes) to produce therapeutic blue light.

Performance Data

Performance data was submitted with this 510(k) notification to support the determination of substantial equivalence for the Tria Sapphire relative to its predicate device.

Non-Clinical:

Performance testing was conducted to demonstrate that the Tria Sapphire performs according to specifications and functions as intended. The Sapphire device was tested and found to be compliant with the following:

- Electrical safety and essential performance (IEC 60601-1)
- Electromagnetic compatibility (IEC 60601-1-2)
- Biocompatibility (ISO 10993-5 & 10993-10)
- Software verification and validation testing

Clinical:

A 60-subject, all-comers OTC usability study was conducted. Subjects demonstrated the ability to (a) make the correct self-selection decision (mild to moderate inflammatory acne), (b) use the device properly and (c) comprehend key directions and warnings according to the Sapphire labeling. No safety issues were identified. Usability results were consistent with the predicate ATS-1 OTC device and are appropriate for over-the-counter clearance.

Substantial Equivalence

The Tria Sapphire is substantially equivalent to the legally marketed ATS-1 OTC blue light device (K090312). It has the same general intended use and indication for use, the same principles of operation and treatment method, and substantially similar technological characteristics as the predicate. The key technical parameters effecting safety and efficacy are identical to the predicate. 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 predicate. Therefore, Tria Sapphire is substantially equivalent.