



# U.S. Department of Health & Human Services

---

Food and Drug Administration

## SAVE REQUEST

**USER:** (jsh)  
**FOLDER:** K090820 - 360 pages  
**COMPANY:** SPECTRAGENICS, INC. (SPECTRAGENICS)  
**PRODUCT:** POWERED LASER SURGICAL INSTRUMENT (GEX)  
**SUMMARY:** Product: TRIA HAIR REMOVAL LASER SYSTEM

**DATE REQUESTED:** Oct 5, 2011

**DATE PRINTED:** Oct 5, 2011

**Note:** Printed



DEC 23 2009

**TRIA Laser Hair Removal System (TRIA)**

K090820

**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  
Facsimile: 925-701-2598  
Contact Person: Lisa D. Parr, Pharm.D.  
Date Prepared: December 7, 2009

**Name of Device and Name/Address of Sponsor**

TRIA Laser Hair Removal System (TRIA)  
TRIA Beauty, Inc.  
5880 W. Las Positas Blvd., Suite 52  
Pleasanton, CA 94588-8552

**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**

SpectraGenics Spectra Hair Removal Laser System (K053527)  
Star Medical Technologies LightSheer Pulsed Diode Array Laser System (K982940)  
Home Skinovations Flash N' Go (K082298)

### **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.

### **Technological Characteristics**

TRIA is a semiconductor diode laser system that delivers infrared light at a wavelength of nominally 800 nm.

### **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**

TRIA has the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate devices. Any minor differences between the TRIA 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 TRIA is as safe and effective as its predicate devices for the stated indications. Thus, TRIA is substantially equivalent.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

DEC 23 2009

TRIA Beauty, Inc.  
% Tobin C. Island, Ph.D.  
Executive Vice President  
5880 W. Las Positas Boulevard, Suite 52  
Pleasanton, California 94588

Re: K090820

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: December 7, 2009

Received: December 7, 2009

Dear Dr. 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.

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

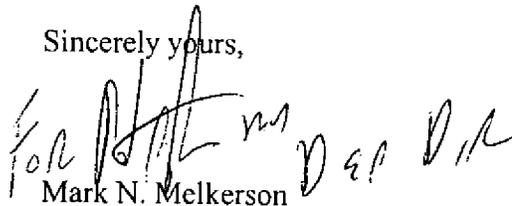
Page 2 - Tobin C. Island, Ph.D.

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" (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/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,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name. The signature is stylized and includes some additional scribbles to the right.

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):** K090820

**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.

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 Page \_\_ of \_\_  
and Restorative Devices

510(k) Number

  K090820







































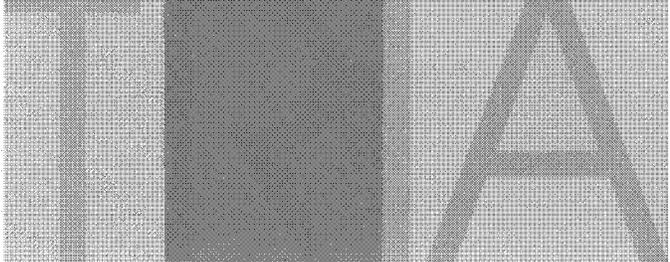












K090820/A'

FDA CDRH DMC

NOV 20 2009

Received

November 18, 2009

*BY HAND DELIVERY*

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center - WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Attn: Richard Weiblinger (Room 1426)

**Re:** TRIA Beauty, Inc., TRIA Hair Reduction System (K090820)

Dear Mr. Weiblinger:

Presently, I am the official contact for the TRIA Beauty, Inc., TRIA Hair Reduction System (K090820). Please add John J. Smith, M.D., J.D., and Jonathan S. Kahan of Hogan & Hartson LLP as additional contacts for this submission.

Sincerely,

Tobin Island, Ph.D.  
Executive Vice President  
TRIA Beauty, Inc.

K36





Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

DEC 23 2009

TRIA Beauty, Inc.  
% Tobin C. Island, Ph.D.  
Executive Vice President  
5880 W. Las Positas Boulevard, Suite 52  
Pleasanton, California 94588

Re: K090820

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: December 7, 2009

Received: December 7, 2009

Dear Dr. 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.

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

DJA X00002

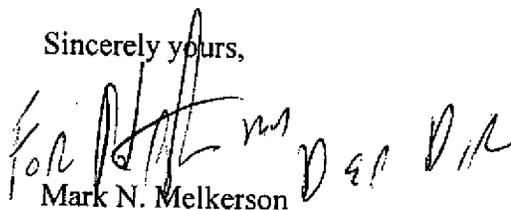
Page 2 - Tobin C. Island, Ph.D.

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,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', with some additional scribbles and initials to the right.

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):** K090820

**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.

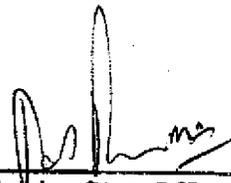
Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

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 Page \_\_\_ of \_\_\_  
and Restorative Devices

510(k) Number  K090820



U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center - WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

December 03, 2009

SPECTRAGENICS, INC.  
5880 W. LAS POSITAS BLVD SUITE 52  
PLEASANTON, CALIFORNIA 94588-8522  
UNITED STATES  
ATTN: TOBIN C. ISLAND

510k Number: K090820

Product: TRIA HAIR REMOVAL LASER SYSTEM

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

DJA X00070

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman  
Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and Radiological Health



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

## Public Health Service

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

November 19, 2009

SPECTRAGENICS, INC.  
5880 W. LAS POSITAS BLVD SUITE 52  
PLEASANTON, CALIFORNIA 94588-8522  
UNITED STATES  
ATTN: TOBIN C. ISLAND

510k Number: K090820

Product: TRIA HAIR REMOVAL LASER

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

DJA 00108



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, Maryland 20850

July 10, 2009

SPECTRAGENICS, INC.  
5880 W. LAS POSITAS BLVD SUITE 52  
PLEASANTON, CALIFORNIA 94588-8522  
UNITED STATES  
ATTN: TOBIN C. ISLAND

510k Number: K090820  
Product: TRIA HAIR REMOVAL LASER SYSTEM  
Extended Until: 08/10/2009

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(1)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman  
Supervisory Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and Radiological Health

K090820

# HOGAN & HARTSON

FDA CDHRC DMC

JUL 09 2009

Received

Hogan & Hartson LLP  
Columbia Square  
555 Thirteenth Street, NW  
Washington, DC 20004  
+1.202.637.5600 Tel  
+1.202.637.5910 Fax

www.hhlaw.com

Jonathan S. Kahan  
Partner  
1.202.637.5794  
JSKahan@hhlaw.com

July 9, 2009

## **BY HAND DELIVERY**

510(k) Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Office of Device Evaluation  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD 20850

Attn: Richard Weiblinger (HFZ-401)

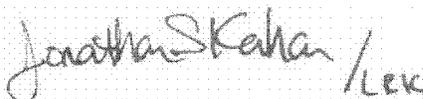
**Re: Request for Extension of Time to Respond to FDA's Request for Additional Information regarding the 510(k) Notice for the TRIA Hair Removal System (K090820)**

Dear Mr. Weiblinger:

On behalf of our client, Tria Beauty, Inc. ("Tria Beauty" or the "company"), we are writing to provide the U.S. Food and Drug Administration ("FDA" or the "agency") with the company's request for additional time to respond to FDA's request for additional information regarding the 510(k) notice for the TRIA Hair Removal System (K090820).

Should you have any questions regarding these documents, please contact me at the number above or John Smith at 202-637-3638.

Sincerely,



Jonathan S. Kahan

Enclosures

cc: Lisa Parr  
John J. Smith, MD, JD, Hogan & Hartson, LLP

K51

DJA X00110



July 9, 2009

Lisa Parr, Pharm. D.  
Vice President, Regulatory Affairs  
TRIA Beauty, Inc.  
5880 W. Las Positas Blvd., Suite 52  
Pleasanton, CA 94588  
(925) 701-2539

***BY HAND DELIVERY***

510(k) Document Mail Center (HFZ-401)  
Office of Device Evaluation  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD 20850

**VIA MESSENGER AND ELECTRONIC MAIL**

Attention: Richard Weiblinger (HFZ-410)

**Re: Request for Extension of Time to Respond to FDA's Request for Additional Information Regarding the 510(k) Premarket Notification for TRIA Hair Removal Laser System (K090820)**

Dear Mr. Weiblinger:

The purpose of this letter is to request that the Food and Drug Administration ("FDA" or "the agency") grant a 60-day extension of time for TRIA Beauty, Inc. to respond to FDA's May 26, 2009, letter requesting additional information with regard to the 510(k) premarket notification for the TRIA Hair Removal Laser System (K090820). The company's response is currently due on June 26, 2009. This extension of the deadline to August 26, 2009, is necessary in order for the company to fully respond to the issues identified in the May 26, letter.

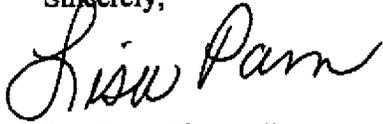
Please contact me at the above number if you have any questions regarding this request. Thank you in advance for your assistance.



DJA X00111

July 9, 2009  
Page 2

Sincerely,

A handwritten signature in black ink that reads "Lisa Parr". The signature is written in a cursive, flowing style.

Lisa Parr, Pharm. D.  
Vice President, Regulatory Affairs

Enclosures

cc:



May 26, 2009

SPECTRAGENICS, INC.  
5880 W. LAS POSITAS BLVD SUITE 52  
PLEASANTON, CALIFORNIA 94588-8522  
UNITED STATES  
ATTN: TOBIN C. ISLAND

510k Number: K090820

Product: TRIA HAIR REMOVAL LASER SYSTEM

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html).

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

DJA X00113

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman  
Supervisory Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and Radiological Health



March 26, 2009

SPECTRAGENICS, INC.  
5880 W. LAS POSITAS BLVD SUITE 52  
PLEASANTON, CALIFORNIA 94588-8522  
UNITED STATES  
ATTN: TOBIN C. ISLAND

510k Number: K090820

Received: 3/26/2009

Product: TRIA HAIR REMOVAL LASER SYSTEM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/cdrh/mdufma/index.html> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf>) accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

DJA X00124

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007"

([http://www.fda.gov/oc/initiatives/fdaaa/guidance\\_certifications.html](http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html)). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1655.pdf>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at [www.fda.gov/cdrh/ode/guidance/1567.html](http://www.fda.gov/cdrh/ode/guidance/1567.html). Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at [www.fda.gov/cdrh/electsub.html](http://www.fda.gov/cdrh/electsub.html). In addition, the 510(k) Program Video is now available for viewing on line at [www.fda.gov/cdrh/video/510k.wmv](http://www.fda.gov/cdrh/video/510k.wmv).

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice [www.fda.gov/cdrh/devadvice/](http://www.fda.gov/cdrh/devadvice/)". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman  
Supervisory Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and Radiological Health

1090820

4 510(K) COVER LETTER

FDA CDRH DMC  
MAR 26 2009  
Received

March 25, 2009

By Messenger

510(k) Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, Maryland 20850

Attn: Neil R. Ogden, General Surgery Devices Branch (HFZ-410)

Re: Premarket Notification for TRIA Beauty, Inc.'s TRIA Hair Removal Laser System

Dear Mr. Ogden:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), TRIA Beauty, Inc. (formerly SpectraGenics, Inc.)<sup>1</sup> ("TRIA Beauty" or the "Company") is submitting the attached premarket notification ("510(k) Notification") for its TRIA Hair Removal Laser System ("TRIA"). (b)(4)

(b)(4)

As explained in detail in the attached 510(k) Notification, the TRIA is substantially equivalent to the Company's Spectra Hair Removal Laser System (K053527) ("Spectra"), the Star Medical Technologies LightSheer (K982940) ("LightSheer"), and the Home Skinovations Flash N' Go (K082298) ("Flash N' Go"). Further, clinical trials have been conducted to demonstrate the safety and efficacy of the TRIA (b)(4)

(b)(4) as is discussed in the Performance Testing section of this submission. The study results indicate that the TRIA (b)(4)  
(b)(4)

TRIA Beauty's TRIA is a pulsed diode laser system classified as a laser surgical instrument for use in general and plastic surgery and dermatology (product code GEX) per 21 C.F.R. 878.4810.

<sup>1</sup> SpectraGenics, Inc. officially changed its name to TRIA Beauty on August 1, 2008.

To conform with the Food and Drug Administration's ("FDA" or the "Agency") August 12, 2005, Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s, the principal factors concerning the design and use of the TRIA are set forth in the following table of FDA questions.

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?		X
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	X	
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

In accordance with the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), TRIA Beauty has submitted the required application fee. A copy of the User Fee Cover Sheet is provided with the attached premarket notification. Per FDA's instructions, the Company has also included an electronic copy of this submission, which is an exact duplicate of the paper submission.

TRIA Beauty considers its intent to market the TRIA as confidential commercial information. The Company has not disclosed its intent to market this device to anyone except its employees, others with a financial interest in the Company, its advertising or law firms, and its consultants. The Company, therefore requests that FDA not disclose the existence of this application until such time as final action on the submission is taken.

In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61 and, therefore, is not disclosable under the Freedom of Information Act, even after the existence of this application becomes public. We ask that you consult with the Company as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

We trust that the information provided in this 510(k) notice is sufficient for FDA to find the TRIA substantially equivalent to its predicate devices for the listed indication. If you have any additional questions regarding the 510(k) notice, please contact me at (925) 701-2553 or by

email at toby@triabeauty.com or contact our regulatory counsel Jonathan Kahan or John Smith of Hogan & Hartson LLP. Upon clearance of the device, please fax the substantial equivalence letter to me at (925) 701-2598.

Sincerely,

A handwritten signature in black ink, appearing to read 'Tobin C. Island', written in a cursive style.

Tobin C. Island, Ph.D.

**Attachments**

ccs: Robert E. Grove, Ph.D., Chief Technology Officer, TRIA Beauty, Inc.  
Jonathan S. Kahan, J.D., Hogan & Hartson LLP, Regulatory Counsel  
John J. Smith, M.D., J.D., Hogan & Hartson LLP, Regulatory Counsel

**TRIA Beauty, Inc.**  
**TRIA Hair Removal Laser System (Expanded Indications)**  
**510(k) Premarket Notification**

**TRIA Beauty, Inc.**  
**5880 W. Las Positas Blvd., Ste 52**  
**Pleasanton, CA 94588**

## TABLE OF CONTENTS

<u>SEC</u>	<u>TITLE</u>	<u>PG</u>
1	MEDICAL DEVICE USER FEE .....	2
2	CDRH PREMARKET REVIEW SUBMISSION COVER SHEET .....	5
3	CERTIFICATION OF COMPLIANCE WITH CLINICALTRIALS.GOV .....	11
4	510(K) COVER LETTER.....	13
5	INDICATIONS FOR USE STATEMENT.....	16
6	510(K) SUMMARY .....	18
7	TRUTHFUL AND ACCURATE STATEMENT.....	21
8	FINANCIAL DISCLOSURES .....	23
9	DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS .....	25
10	EXECUTIVE SUMMARY .....	30
11	DEVICE DESCRIPTION.....	31
A	INTENDED Use/INDICATIONS FOR USE	
B	TECHNOLOGICAL CHARACTERISTICS	
C	PRINCIPLES OF OPERATION	
D	LASER CLASSIFICATION AND EYE SAFETY	
12	SUBSTANTIAL EQUIVALENCE .....	35
A	INTENDED Use/ INDICATIONS FOR USE	
B	TECHNOLOGICAL CHARACTERISTICS	
C	PRINCIPLES OF OPERATION	
D	CONCLUSION	
13	LABELING.....	39
14	STERLIZATION AND SHELF LIFE.....	40
15	BIOCOMPATIBILITY.....	41
16	SOFTWARE.....	43
17	ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY .....	44
18	PERFORMANCE TESTING - CLINICAL .....	45
19	ATTACHMENTS.....	48
A	PROPOSED DRAFT LABELING	
B	FINAL REPORT FOR THE (b)(4) CLINICAL STUDY	

## **1        MEDICAL DEVICE USER FEE**

The Company has remitted the appropriate Medical Device User Fee concurrent with this submission to the Food and Drug Administration, P.O. Box 956733, St. Louis. A copy of the Medical Device User Fee Cover Pages is provided on the following pages.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION  
MEDICAL DEVICE USER FEE COVER SHEET**

**PAYMENT IDENTIFICATION NUMBER:**  
(b)(4)  
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <http://www.fda.gov/oc/mdufma/coversheet.html>

**1. COMPANY NAME AND ADDRESS**  
(include name, street address, city state, country, and post office code)

TRIA BEAUTY INC  
5880 WEST LAS POSITAS BLVD  
SUITE 52  
PLEASANTON CA 94588  
US

**1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)**  
(b)(4)

**2. CONTACT NAME**  
Raymond Lee

**2.1 E-MAIL ADDRESS**  
ray@triabeauty.com

**2.2 TELEPHONE NUMBER (include Area code)**  
925-701-2554

**2.3 FACSIMILE (FAX) NUMBER (Include Area code)**  
925-701-2598

**3. TYPE OF PREMARKET APPLICATION** (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <http://www.fda.gov/oc/mdufma>)

- Select an application type:
- Premarket notification(510(k)); except for third party
  - 513(g) Request for Information
  - Biologics License Application (BLA)
  - Premarket Approval Application (PMA)
  - Modular PMA
  - Product Development Protocol (PDP)
  - Premarket Report (PMR)
  - Annual Fee for Periodic Reporting (APR)
  - 30-Day Notice

- 3.1 Select a center**
- CDRH
  - CBER
- 3.2 Select one of the types below**
- Original Application
- Original Application
- Supplement Types:
- Efficacy (BLA)
  - Panel Track (PMA, PMR, PDP)
  - Real-Time (PMA, PMR, PDP)
  - 180-day (PMA, PMR, PDP)

**4. ARE YOU A SMALL BUSINESS?** (See the instructions for more information on determining this status)

(b)(4)

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <http://www.fda.gov/cdrh/mdufma> for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

This application is the first PMA submitted by a qualified small business, including any affiliates

The sole purpose of the application is to support conditions of use for a pediatric population

This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

YES       NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4)

18-Feb-2009

REPORT SHEET

"Close Window" Print Cover sheet

**2 CDRH PREMARKET REVIEW SUBMISSION COVER SHEET**

The CDRH Premarket Review Submission Cover Sheet is provided on the following pages.

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
**FOOD AND DRUG ADMINISTRATION**  
**CDRH PREMARKET REVIEW SUBMISSION COVER SHEET**

Form Approval  
 OMB No. 9010-0120  
 Expiration Date: August 31, 2010.  
 See OMB Statement on page 5.

Date of Submission March 25, 2009	User Fee Payment ID Number MD6041356-956733	FDA Submission Document Number (if known)
--------------------------------------	--	---

**SECTION A TYPE OF SUBMISSION**

<p><b>PMA</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<p><b>PMA &amp; HDE Supplement</b></p> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	<p><b>PDP</b></p> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<p><b>510(k)</b></p> <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<p><b>Meeting</b></p> <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
<p><b>IDE</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<p><b>Humanitarian Device Exemption (HDE)</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<p><b>Class II Exemption Petition</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<p><b>Evaluation of Automatic Class III Designation (De Novo)</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<p><b>Other Submission</b></p> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission?  Yes  No (If Yes, please complete Section I, Page 5)

**SECTION B SUBMITTER, APPLICANT OR SPONSOR**

Company / Institution Name TRIA Beauty, Inc.		Establishment Registration Number (if known) 3005572989	
Division Name (if applicable)		Phone Number (including area code) (925) 701-2553	
Street Address 5880 W. Las Positas Blvd. Ste 52		FAX Number (including area code) (925) 701-2598	
City Pleasanton	State / Province CA	ZIP/Postal Code 94588	Country USA
Contact Name Tobin C. Island, Ph.D.			
Contact Title Executive Vice President		Contact E-mail Address toby@triabeauty.com	

**SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)**

Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

**SECTION D1**

**REASON FOR APPLICATION - PMA, PDP, OR HDE**

<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason ( <i>specify</i> ):		

**SECTION D2**

**REASON FOR APPLICATION – IDE**

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor  <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Other Reason ( <i>specify</i> ):		

**SECTION D3**

**REASON FOR SUBMISSION - 510(k)**

<input type="checkbox"/> New Device	<input checked="" type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input type="checkbox"/> Other Reason ( <i>specify</i> ):		

**SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS**

Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	GEX	2		3		4		
5		6		7		8		

Information on devices to which substantial equivalence is claimed (*if known*)

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K053527	1	Spectra Hair Removal Laser System	1	SpectraGenics, Inc.
2	K982940	2	LightSheer™ Pulsed Diode Array Laser	2	Star Medical Technologies, Inc.
3	K082298	3	Flash N' Go	3	Home Skinovations, Ltd.
4					
5		5		5	
6		6		6	

**SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification

	Trade or Proprietary or Model Name for This Device		Model Number
1	TRIA Hair Removal Laser System	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions (*regardless of outcome*)

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

Laboratory Testing   
  Animal Trials   
  Human Trials

**SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS**

Product Code GEX	C.F.R. Section ( <i>if applicable</i> ) 878.4810	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General and Plastic Surgery Devices		

Indications (*from labeling*)

TRIA is an over-the-counter device intended for removal of unwanted hair. TRIA is also intended for permanent hair reduction.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

**SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number 3005572989	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name TRIA Beauty, Inc.		Establishment Registration Number 3005572989		
Division Name (if applicable)		Phone Number (including area code) (925) 701-2549		
Street Address 5880 W. Las Positas Blvd. Ste. 52		FAX Number (including area code) (925) 701-2598		
City Pleasanton		State / Province CA	ZIP/Postal Code 94588	Country USA
Contact Name Tobin C. Island, Ph.D.		Contact Title Executive Vice President		Contact E-mail Address toby@triabeauty.com

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name (if applicable)		Phone Number (including area code) ( )		
Street Address		FAX Number (including area code) ( )		
City		State / Province	ZIP/Postal Code	Country
Contact Name		Contact Title		Contact E-mail Address

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name (if applicable)		Phone Number (including area code) ( )		
Street Address		FAX Number (including area code) ( )		
City		State / Province	ZIP/Postal Code	Country
Contact Name		Contact Title		Contact E-mail Address

**SECTION I**

**UTILIZATION OF STANDARDS**

1	Standards No.	Standards Organization	Standards Title	Version	Date
	IEC 60601-1	IEC	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	1988+A1:1991+A2 1995	1998
2	Standards No.	Standards Organization	Standards Title	Version	Date
	EN 60601-1-2	EN	Medical electrical equipment – Part 2: Collateral standard: Electromagnetic compatibility.	2001 W/A1:06 FCC Part 18	2001
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

**Please include any additional standards to be cited on a separate page.**

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration  
 CDRH (HFZ-342)  
 9200 Corporate Blvd.  
 Rockville, MD 20850

*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 control*

### **3 CERTIFICATION OF COMPLIANCE WITH CLINICALTRIALS.GOV**

A completed copy of the Certification of Compliance with ClinicalTrials.gov Data Bank, FDA Form 3674, is provided on the following page.



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with  
Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

**SPONSOR / APPLICANT / SUBMITTER INFORMATION**

1. NAME OF SPONSOR/APPLICANT/SUBMITTER TRIA Beauty, Inc.	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES 03/25/2009
3. ADDRESS (Number, Street, State, and ZIP Code) 5880 W Las Positas Blvd, Ste 52 Pleasanton, CA 94588	4. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 925-701-2553 (Fax) 925-701-2598

**PRODUCT INFORMATION**

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)  
**FOR DEVICES:** Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)  
(Attach extra pages as necessary)

TRIA Hair Removal Laser System

**APPLICATION / SUBMISSION INFORMATION**

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES <input type="checkbox"/> IND <input type="checkbox"/> NDA <input type="checkbox"/> ANDA <input type="checkbox"/> BLA <input type="checkbox"/> PMA <input type="checkbox"/> HDE <input checked="" type="checkbox"/> 510(k) <input type="checkbox"/> PDP <input type="checkbox"/> Other
7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)
8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

**CERTIFICATION STATEMENT / INFORMATION**

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)

A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

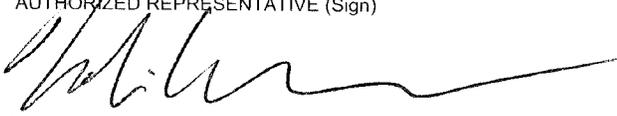
B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)

NCT Number(s): \_\_\_\_\_

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.  
**Warning:** A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Tobin Island (Title) Executive Vice President
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12) TRIA Beauty, Inc. 5880 W Las Positas Blvd, Ste 52 Pleasanton, CA 94588	14. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 925-701-2553 (Fax) 925-701-2598
	15. DATE OF CERTIFICATION 03/25/2009

**4 510(K) COVER LETTER**

March 25, 2009

*By Messenger*

510(k) Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, Maryland 20850

Attn: Neil R. Ogden, General Surgery Devices Branch (HFZ-410)

**Re: Premarket Notification for TRIA Beauty, Inc.’s TRIA Hair Removal Laser System**

Dear Mr. Ogden:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (“FDC Act”), TRIA Beauty, Inc. (formerly SpectraGenics, Inc.)<sup>1</sup> (“TRIA Beauty” or the “Company”) is submitting the attached premarket notification (“510(k) Notification”) for its TRIA Hair Removal Laser System (“TRIA”). (b)(4)

(b)(4)

As explained in detail in the attached 510(k) Notification, the TRIA is substantially equivalent to the Company’s Spectra Hair Removal Laser System (K053527) (“Spectra”), the Star Medical Technologies LightSheer (K982940) (“LightSheer”), and the Home Skinovations Flash N’ Go (K082298) (“Flash N’ Go”). Further, clinical trials have been conducted to demonstrate the safety and efficacy of the TRIA (b)(4)

(b)(4) as is discussed in the Performance Testing section of this submission. The study results indicate that the TRIA (b)(4)

(b)(4)

TRIA Beauty’s TRIA is a pulsed diode laser system classified as a laser surgical instrument for use in general and plastic surgery and dermatology (product code GEX) per 21 C.F.R. 878.4810.

---

<sup>1</sup> SpectraGenics, Inc. officially changed its name to TRIA Beauty on August 1, 2008.

To conform with the Food and Drug Administration’s (“FDA” or the “Agency”) August 12, 2005, Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s, the principal factors concerning the design and use of the TRIA are set forth in the following table of FDA questions.

<b>Question</b>	<b>YES</b>	<b>NO</b>
Is the device intended for prescription use (21 CFR 801 Subpart D)?		X
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	X	
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

In accordance with the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), TRIA Beauty has submitted the required application fee. A copy of the User Fee Cover Sheet is provided with the attached premarket notification. Per FDA’s instructions, the Company has also included an electronic copy of this submission, which is an exact duplicate of the paper submission.

TRIA Beauty considers its intent to market the TRIA as confidential commercial information. The Company has not disclosed its intent to market this device to anyone except its employees, others with a financial interest in the Company, its advertising or law firms, and its consultants. The Company, therefore requests that FDA not disclose the existence of this application until such time as final action on the submission is taken.

In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61 and, therefore, is not disclosable under the Freedom of Information Act, even after the existence of this application becomes public. We ask that you consult with the Company as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

We trust that the information provided in this 510(k) notice is sufficient for FDA to find the TRIA substantially equivalent to its predicate devices for the listed indication. If you have any additional questions regarding the 510(k) notice, please contact me at (925) 701-2553 or by

email at toby@triabeauty.com or contact our regulatory counsel Jonathan Kahan or John Smith of Hogan & Hartson LLP. Upon clearance of the device, please fax the substantial equivalence letter to me at (925) 701-2598.

Sincerely,

A handwritten signature in black ink, appearing to read 'Tobin C. Island', with a long, sweeping horizontal stroke extending to the right.

Tobin C. Island, Ph.D.

**Attachments**

ccs: Robert E. Grove, Ph.D., Chief Technology Officer, TRIA Beauty, Inc.  
Jonathan S. Kahan, J.D., Hogan & Hartson LLP, Regulatory Counsel  
John J. Smith, M.D., J.D., Hogan & Hartson LLP, Regulatory Counsel

## **5 INDICATIONS FOR USE STATEMENT**

The Company's Indications for Use Statement for the TRIA is provided on the following page.

### Indications for Use Statement

510(k) Number (if known): \_\_\_\_\_

Device Name: TRIA

Indications for Use:

(b)(4)

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)

Page \_\_\_ of \_\_\_

**6        510(K) SUMMARY**

The Company's 510(k) Summary is provided on the following pages.

## 510(k) SUMMARY

### TRIA Hair Removal Laser System

#### 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  
Facsimile: 925-701-2598  
Contact Person: Tobin C. Island, Ph.D.  
Date Prepared: March 25, 2009

#### Name of Device and Name/Address of Sponsor

TRIA Hair Removal Laser System  
TRIA Beauty, Inc.  
5880 W. Las Positas Blvd., Suite 52  
Pleasanton, CA 94588-8552

#### 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

SpectraGenics Spectra Hair Removal Laser System (K053527)  
Star Medical Technologies LightSheer Pulsed Diode Array Laser System (K982940)  
Home Skinovations Flash N' Go (K082298)

## Intended Use / Indications for Use

(b)(4)

## Technological Characteristics

(b)(4)

(b)(4)

The TRIA Hair Removal Laser is a semiconductor diode laser system that delivers infrared light at a wavelength of nominally 800 nm. (b)(4)

(b)(4)

## Performance Data

Clinical trials have been conducted to demonstrate the safety and efficacy of the TRIA for home use for (b)(4)

indicate that the TRIA (b)(4)

(b)(4)

## Substantial Equivalence

The TRIA is as safe and effective as the predicate devices. The TRIA has the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate devices. Any minor differences between the TRIA 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 the TRIA is as safe and effective as its predicate devices for the stated indications. Thus, the TRIA is substantially equivalent.

**7 TRUTHFUL AND ACCURATE STATEMENT**

The Company's signed Truthful and Accurate statement is included on the following page.

**PREMARKET NOTIFICATION**

**TRUTHFUL AND ACCURATE STATEMENT**

**(As Required by 21 C.F.R. § 807.87(k))**

I certify that, in my capacity as Executive Vice President of TRIA Beauty, Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification for the TRIA Hair Removal Laser System are truthful and accurate and that no material fact has been omitted.



\_\_\_\_\_  
(Signature)

Tobin C. Island, Ph.D.  
Executive Vice President, TRIA Beauty, Inc.

March 25, 2009  
(Date)

## **8 FINANCIAL DISCLOSURES**

TRIA Beauty is submitting clinical data to support this 510(k) notice. The Company is providing a certification to the absence of any financial arrangements by the investigator on the following page.

# CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

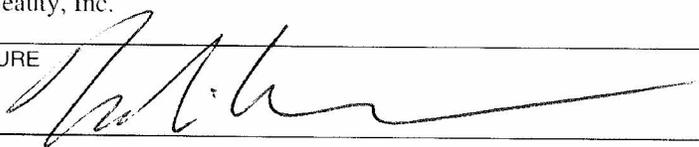
Please mark the applicable checkbox.

- (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators	(b)(4)	

- (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

- (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME Tobin C. Island	TITLE Executive Vice President
FIRM / ORGANIZATION TRIA Beauty, Inc.	
SIGNATURE 	DATE 3/25/09

### Paperwork Reduction Act Statement

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 control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services  
Food and Drug Administration  
5600 Fishers Lane, Room 14C-03  
Rockville, MD 20857

## 9 DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

The TRIA complies with IEC 60601-1 and EN 60601-1-2. (b)(4)

(b)(4)

(b)(4)

(b)(4)

Note

that the EN 60601-1-2 standard is materially equivalent to the IEC 60601-1-2 standard. A standards data report, form FDA-3654, for each of these standards listed above is provided in the following pages.

(b)(4)

, the TRIA also complies with the requirements of 21 C.F.R. Subchapter J (Radiological Health), which includes, but is not limited to, Part 1040, "Performance Standards for Radiological Products," including 1040.10 (Laser products) and 1040.11 (Specific purpose laser products).

Department of Health and Human Services  
 Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(K)**  
*(To be filled in by applicant)*

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional
  Special
  Abbreviated

STANDARD TITLE <sup>1</sup>  
 IEC 60601-1:1988 +A1:1991 +A2: 1995 Medical electrical equipment Part 1: General requirements for safety

**Please answer the following questions** Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 5-4

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....      

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....         
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....      

Does this standard include acceptance criteria? .....         
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of the standard?.....         
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? .....         
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>?.....      

Were deviations or adaptations made beyond what is specified in the FDA SIS? .....         
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....         
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....         
 If yes, was the guidance document followed in preparation of this 510k?.....      

Title of guidance: \_\_\_\_\_

<p><sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p><sup>2</sup> Authority [21 U.S.C. 360d], <a href="http://www.fda.gov/cdrh/stdsprog.html">www.fda.gov/cdrh/stdsprog.html</a></p> <p><sup>3</sup> <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a></p> <p><sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or</p>	<p>certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.</p> <p><sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a></p> <p><sup>6</sup> The online search of CDRH Guidance Documents can be found at <a href="http://www.fda.gov/cdrh/guidance.html">www.fda.gov/cdrh/guidance.html</a></p>
---	---

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

IEC 60601-1, MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR SAFETY, 1988; AMENDMENT 1, 1991-11, AMENDMENT 2, 1995.

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	N/A	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

**TYPE OF DEVIATION OR OPTION SELECTED\***

Option selected was CB Scheme as applicable for this device for AU, CA, DK, IL, KR, and US jurisdictions

**DESCRIPTION**

N/A

**JUSTIFICATION**

Appropriate option for this device as applies to US jurisdiction.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

**TYPE OF DEVIATION OR OPTION SELECTED\***

**DESCRIPTION**

**JUSTIFICATION**

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

**TYPE OF DEVIATION OR OPTION SELECTED\***

**DESCRIPTION**

**JUSTIFICATION**

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

\* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

**Paperwork Reduction Act Statement**

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health  
1350 Piccard Drive  
Rockville, MD 20850

*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 control number.*

Department of Health and Human Services  
 Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(K)S**  
*(To be filled in by applicant)*

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional                     
  Special                                     
  Abbreviated

STANDARD TITLE <sup>1</sup>  
 EN 60601-1-2 :2001 +A1:2006 +FCC Part 18, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests (General)

**Please answer the following questions** Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # N/A

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....      

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....         
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....      

Does this standard include acceptance criteria? .....         
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of the standard?.....         
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? .....         
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>?.....      

Were deviations or adaptations made beyond what is specified in the FDA SIS? .....         
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....         
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....         
 If yes, was the guidance document followed in preparation of this 510k?.....      

Title of guidance: \_\_\_\_\_

<p><sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p><sup>2</sup> Authority [21 U.S.C. 360d], <a href="http://www.fda.gov/cdrh/stdsprog.html">www.fda.gov/cdrh/stdsprog.html</a></p> <p><sup>3</sup> <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a></p> <p><sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or</p>	<p>certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.</p> <p><sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a></p> <p><sup>6</sup> The online search of CDRH Guidance Documents can be found at <a href="http://www.fda.gov/cdrh/guidance.html">www.fda.gov/cdrh/guidance.html</a></p>
---	---

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

EN 60601-1-2 :2001 +A1:2006 +FCC PART 18, MEDICAL ELECTRICAL EQUIPMENT - PART 1-2: GENERAL REQUIREMENTS FOR SAFETY - COLLATERAL STANDARD: ELECTROMAGNETIC COMPATIBILITY - REQUIREMENTS AND TESTS (GENERAL)

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	N/A	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

**TYPE OF DEVIATION OR OPTION SELECTED\***

Option selected was to include FCC Part 18 and most recent amendment (2006) with options applicable for this device for US jurisdictions

**DESCRIPTION**

N/A

**JUSTIFICATION**

Appropriate option for this device as applies to US jurisdiction.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

**TYPE OF DEVIATION OR OPTION SELECTED\***

**DESCRIPTION**

**JUSTIFICATION**

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

**TYPE OF DEVIATION OR OPTION SELECTED\***

**DESCRIPTION**

**JUSTIFICATION**

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

\* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

**Paperwork Reduction Act Statement**

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health  
1350 Piccard Drive  
Rockville, MD 20850

*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 control number.*

## 10 EXECUTIVE SUMMARY

The TRIA is a semiconductor pulsed diode laser system for use in laser hair removal that delivers infrared light at a wavelength of nominally 800 nm. The system is comprised of the laser handpiece, skin sensor, and a battery charger. The TRIA is an over-the-counter (“OTC”) device intended to (b)(4)

(b)(4)

The TRIA is substantially equivalent to the Spectra Hair Removal Laser System (K053527) (“Spectra”), the LightSheer Pulsed Diode Array Laser System (K982940) (“LightSheer”), and the Flash ‘N Go (K082298) (“Flash N’ Go”). (b)(4)

(b)(4)

(b)(4)

---

(b)(4)

## 11 DEVICE DESCRIPTION

TRIA's intended use/indications for use, technological characteristics, and principles of operation are described below. (b)(4)

(b)(4)

Drawings of the TRIA System are included in Drawings 1 – 3 below.

### A Intended Use/Indications for Use

(b)(4)

### B Technological Characteristics

The TRIA is a semiconductor pulsed diode laser system that delivers infrared light at a wavelength of nominally 800 nm. The TRIA, (b)(4)

(b)(4) consists of the following key elements:

(i) (b)(4)

(b)(4)

(ii) (b)(4)

(b)(4)

(iii) (b)(4)

(b)(4)

(b)(4)



**C Principles of Operation**

(b)(4)



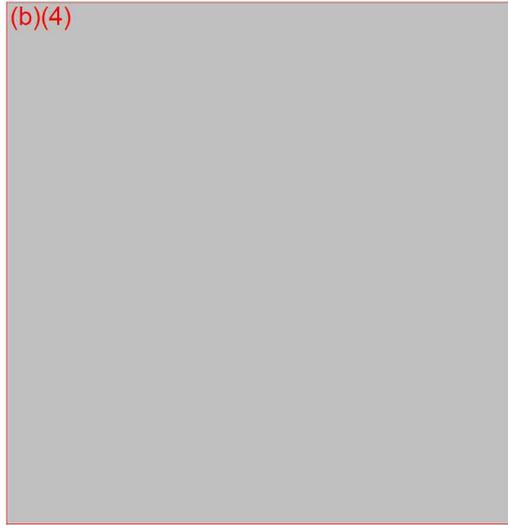
(b)(4)

A large rectangular area of the document is redacted with a solid grey fill. The redaction covers the majority of the upper half of the page.

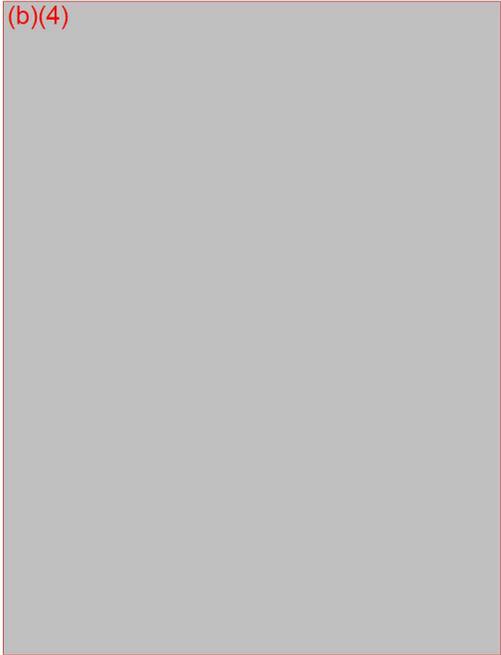
**D Laser Classification and Eye Safety**

(b)(4)

A large rectangular area of the document is redacted with a solid grey fill. This redaction covers the content of the section titled 'D Laser Classification and Eye Safety'.



**Drawing 1:** (b)(4)



**Drawing 3:** (b)(4)



**Drawing 2:** (b)(4)

## 12 SUBSTANTIAL EQUIVALENCE

As explained in detail below, the TRIA is substantially equivalent to other legally marketed light-based hair removal systems. Specifically, the TRIA is substantially equivalent to the Company's Spectra Hair Removal Laser System (K053527) ("Spectra"), Star Medical Technologies LightSheer Pulsed Diode Array Laser System (K982940) ("LightSheer") and Home Skinovations Flash N' Go (K082298) ("Flash N' Go"). (b)(4)

(b)(4)

(b)(4)

These predicates are listed in the comparison table below and the key comparisons of the table are described in more detail below.

### A Intended Use/ Indications for Use

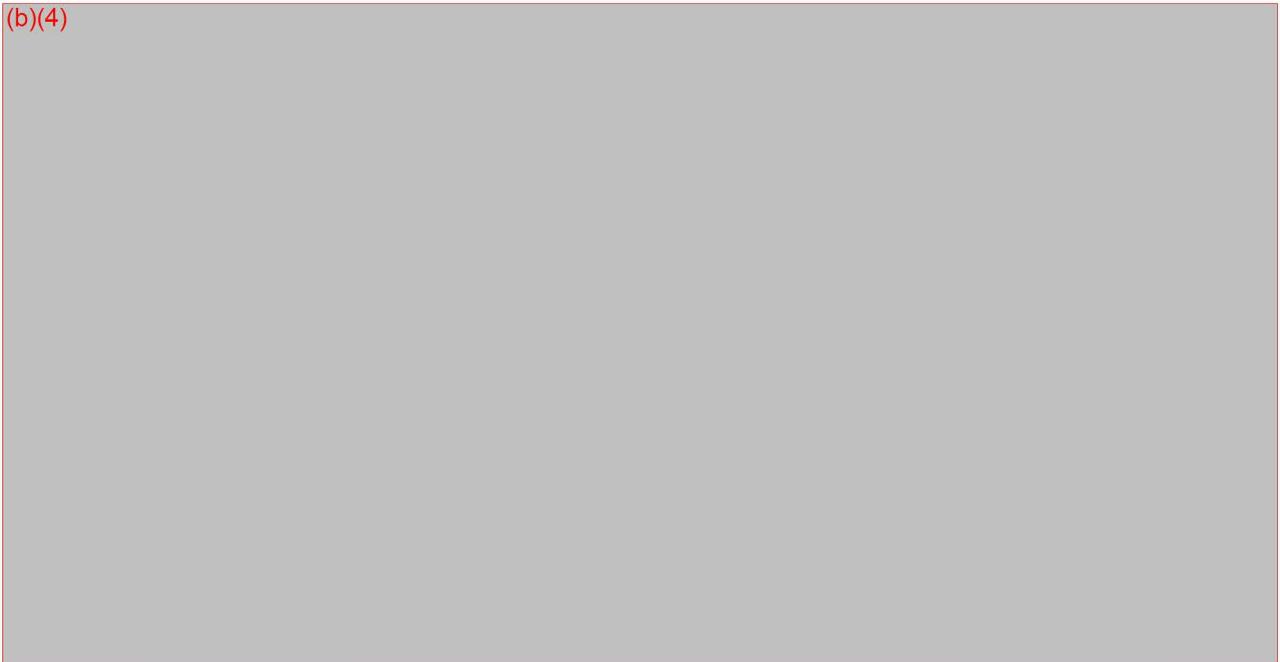
(b)(4)

(b)(4)



**B Technological Characteristics**

(b)(4)



(b)(4)

In light of any minor technological differences between the TRIA and its predicate devices, clinical performance data is provided to further demonstrate that the device is as safe and effective as the predicate devices for its stated indications (See Performance Testing).

### **C Principles of Operation**

(b)(4)

### **D Conclusion**

As demonstrated above, the TRIA and its predicates have the same intended use and similar indications for use. In addition, the TRIA has the same or similar technological characteristics and principles of operation as its predicates. (b)(4)

(b)(4)

(b)(4)

Any differences in indications for use or technological characteristics between the TRIA and its predicates do not alter the device's intended therapeutic effect and do not introduce any new questions of safety and efficacy. Furthermore, the submitted clinical data (described below) demonstrates that the TRIA is as safe and effective as its predicate devices for these expanded indications. Thus, the TRIA is substantially equivalent to the predicate devices.

### Substantial Equivalence Chart

	TRIA Hair Removal Laser System	Spectra Hair Removal Laser System (K053527)	LightSheer™ Pulsed Diode Array Laser (K982940)	Flash N' Go (K082298)
<b>Intended Use</b>	Hair Removal	Hair Removal	Hair Removal	Hair Removal
<b>Indications for Use</b>	(b)(4)	The Spectra Hair Removal Laser System is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments.	The LightSheer is intended to effect temporary hair reduction. The LightSheer™ is also intended to effect stable long-term, or permanent hair reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regime.	The Flash N' Go is an over-the-counter device intended for the removal of unwanted hair.
<b>User Population Fitzpatrick Skin Types</b>	(b)(4)	I-IV	I-VI	I – IV
<b>Rx/OTC</b>	OTC	OTC	Rx	OTC
<b>Eye Safety</b>	(b)(4)	(b)(4)	(b)(4)	(b)(4)
<b>Wavelength</b>	800 nm	800 nm	790–830 nm	475 – 1200 nm (assumed)
<b>Fluence</b>	(b)(4)	(b)(4)	10–100 J/cm <sup>2</sup>	5 – 7 J/cm <sup>2</sup> (assumed)
<b>Energy Source</b>	(b)(4)	(b)(4)	AlGaAs laser	Flashlamp
<b>Electrical Requirements</b>	Battery Operated	Battery Operated	Mains power	Mains power
<b>Epidermal Protection</b>	(b)(4)	(b)(4)	Contact Sapphire	None
<b>Biocompatibility</b>	No known biocompatibility issues	No known biocompatibility issues	No known biocompatibility issues	No known biocompatibility issues
<b>Software</b>	Yes	Yes	Yes	Yes
<b>Sterilization</b>	Not sold sterile	Not sold sterile	Not sold sterile	Not sold sterile

### 13 LABELING

The proposed draft Instructions For Use (IFU) are provided in Attachment A (b)(4)

(b)(4)

## **14        STERILIZATION AND SHELF LIFE**

Like the predicates, the TRIA is not sold sterile, nor is it intended to be sterilized by the user.

The TRIA is not subject to degradation over time; accordingly, the device does not have a labeled shelf-life. The IFU contains user information on shelf-life that is unchanged from that of the previously cleared Spectra device.

**15      BIOCOMPATIBILITY**

(b)(4)



(b)(4)



The Company's biocompatibility certification is provided on the following page.

**Certification of the Biocompatibility of the  
TRIA Beauty, Inc. TRIA Hair Removal Laser System**

(b)(4)

(b)(4)

Thus, the biocompatibility of these components of the TRIA Hair Removal Laser System has been demonstrated (b)(4)

(b)(4)



Signature

---

Tobin C. Island, Ph.D.

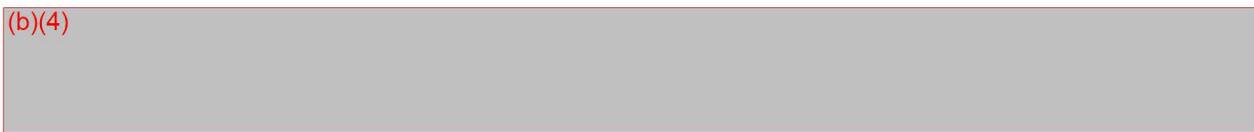
Executive Vice President, TRIA Beauty, Inc.

---

March 25, 2009

**16 SOFTWARE**

(b)(4)



**17 ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY**

(b)(4)

(b)(4)

with the requirements of IEC 60601-1 and EN 60601-1-2 as discussed in the Declarations of Conformity and Summary Reports section above.

**18 PERFORMANCE TESTING - CLINICAL**

(b)(4)



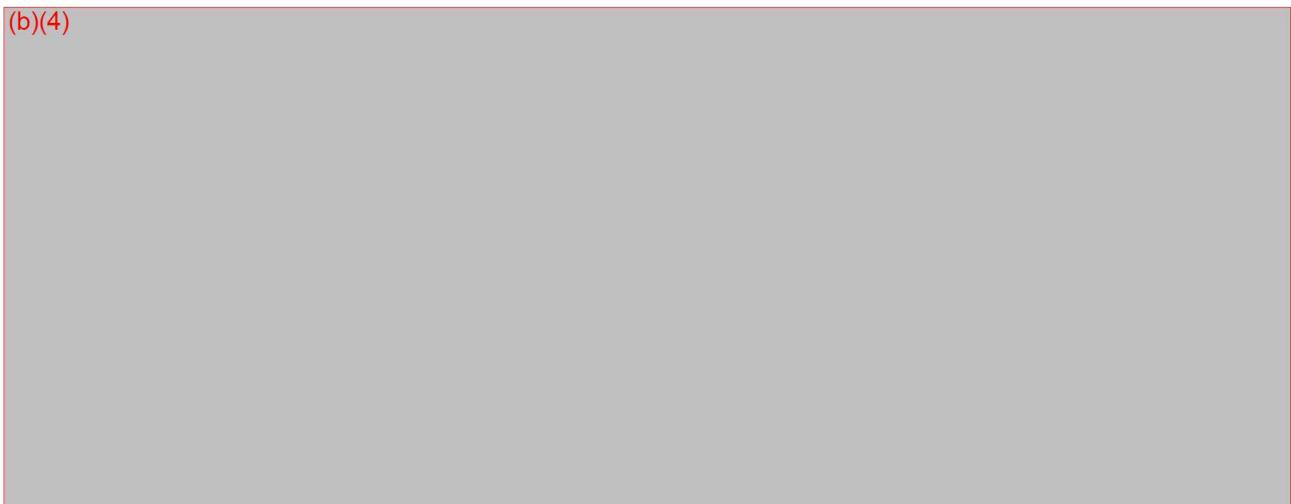
**A. Background**

(b)(4)



**B. Methods**

(b)(4)



(b)(4)



**C. Results**

(b)(4)

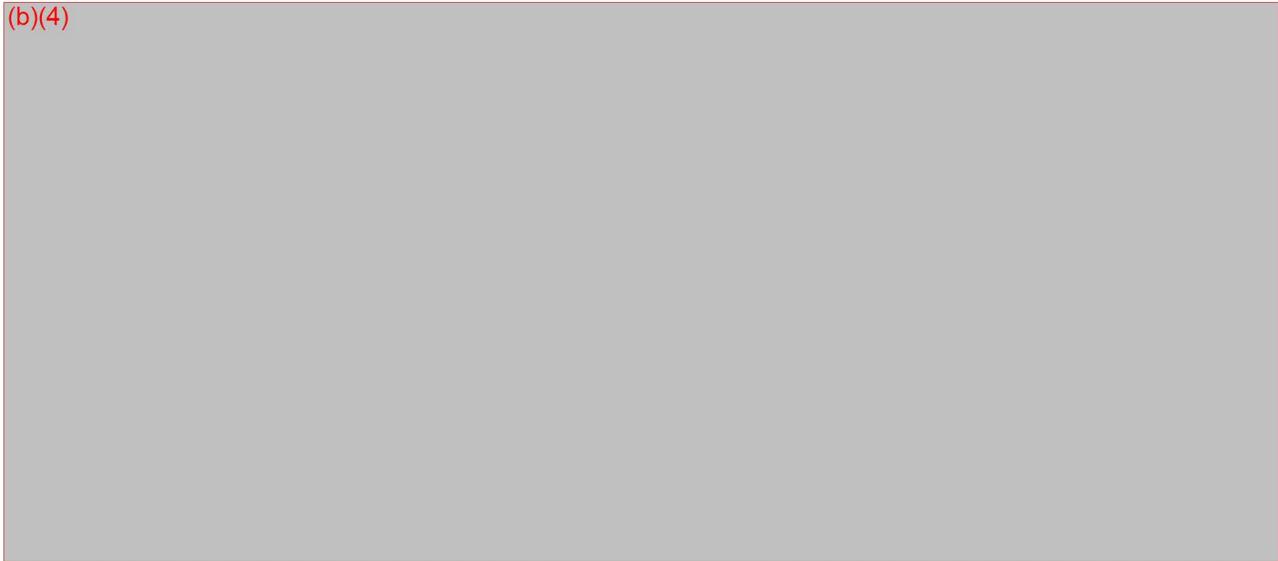


(b)(4)

A large rectangular area of the page is redacted with a solid grey fill. The redaction covers the majority of the upper half of the page.

**D. Conclusion**

(b)(4)

A large rectangular area of the page is redacted with a solid grey fill. This redaction covers the entire content area under the 'D. Conclusion' heading.

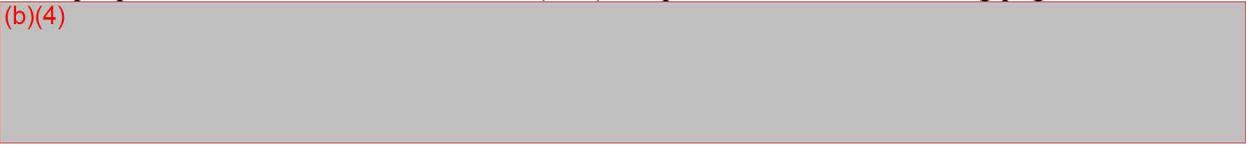
## **19 ATTACHMENTS**

The following pages contain the attachments to this 510(k) Notification, which are independently paginated.

## A Proposed Draft Labeling

The proposed draft Instructions For Use (IFU) are provided on the following pages. (b)(4)

(b)(4)











































**B Final Report for the (b)(4) Clinical Study**

The final report for the (b)(4) clinical study is provided on the following pages.











































































































































































































DJA 300004

# COVER SHEET MEMORANDUM

Office of In Vitro Diagnostics

From: Reviewer Name RICHARD WEIBLINGER  
 Subject: 510(k) Number K090820/5002  
 To: The Record

Please list CTS decision code \_\_\_\_\_

Refused to accept (Note: this is considered the first review cycle. See Screening Checklist [http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0\\_5631/Screening%20Checklist%207%202%2007.doc](http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc))

Hold (Additional Information or Telephone Hold)

Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.) *see PRW*

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	<input checked="" type="checkbox"/>	<input type="checkbox"/>
510(k) Summary / 510(k) Statement	Attach Summary	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Truthful and Accurate Statement	Must be present for a Final Decision	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the device Class III?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, does firm include Class III Summary?	Must be present for a Final Decision	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does firm reference standards? (If yes, please attach form from <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is this a combination product? (Please specify category _____, see <a href="http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4135/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4135/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">http://www.fda.gov/cdrh/ode/guidance/1216.html</a> )		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is this device intended for pediatric use only?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is this a prescription device? (If both prescription & OTC, check both boxes.)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is clinical data necessary to support the review of this 510(k)?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this device include an Animal Tissue Source?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
All Pediatric Patients age <= 21		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Neonate/Newborn (Birth to 28 days)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Infant (29 days - < 2 years old)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Child (2 years - < 12 years old)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Adolescent (12 years - < 18 years old)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age >= 21 (different device design or testing, different protocol procedures, etc.)		<input checked="" type="checkbox"/>	<input type="checkbox"/>

DJA x00005

Transitional Adolescent B (18 -<= 21, No special considerations compared to adults => 21 years old)			
nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <a href="http://www.fda.gov/cdrh/comp/guidance/169.html">http://www.fda.gov/cdrh/comp/guidance/169.html</a> )		Contact OC	

Regulation Number \_\_\_\_\_ Class\* Class II Product Code GEX  
(\*If unclassified, see 510(k) Staff)

Additional Product Codes: \_\_\_\_\_

Review: Richard Pfeiffer C5116 12-23-09  
*acting* (Branch Chief) (Branch Code) (Date)

Final Review: \_\_\_\_\_ (Date)  
 \_\_\_\_\_ (Division Director)

*[Signature]*  
 Dep Director  
 12/23/09

DJA X00007



Food and Drug Administration  
Office of Device Evaluation  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review  
Traditional

K090820s2

Date: December 22, 2009

To: The Record

From: Richard Paul Weiblinger, Biologist

Office: ODE

Division: DSORD/GSDB

510(k) Holder: Spectragenics, Inc.

Device Name: Tria Hair Removal Diode Laser for Over-the-Counter use

Contact: Tobin Island

5880 West Las Positas Blvd.

Pleasanton, CA 94588

925-701-2554

*agree with*

*Dec 23/09*

I. Purpose

The Premarket Notification is a marketing request for the Tria Hair Removal Diode Laser for Over-the-Counter use. Under this submission the sponsor is seeking clearance to market their device for Over-the-Counter use. The device is intended to deliver laser energy intended for patient self use.

The subject device is the 4th laser device for Over-the-Counter use (OTC) which is intended to be used as a patient self-use device for laser hair removal. FDA previously has granted 510(k) marketing clearance for other laser devices for laser hair removal for Over-the-Counter use (see K060839, K053527, and K082298).

The device is a compact, portable, self-contained system which emits light at a wavelength of 800 nm. (b)(4)

(b)(4)

## II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or <u>OTC</u> )	X		
Truthful and Accuracy Statement	X		
510(k) Summary	X		
Standards Form	X		

## III. Device Description

The device is the *Tria Hair Removal Diode Laser for Over-the-Counter use (non-prescription)*. (b)(4)

(b)(4) The firm has provided a comparison table which provides device specification comparisons.

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?	X		
Are "cleaning" instructions included for the end user?			

(b)(4)



**III. 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 growth defined as a long-term, stable reduction in hair counts following a treatment regime.*

(b)(4)



#### IV. Predicate Device Comparison

<b>Device Characteristic</b>	<i>Spectragenics, Inc. Tria Hair Removal Diode Laser for OTC (Over-the-Counter) use K090820</i>	<i>Spectragenics, Inc. Spectra™ Hair Removal Diode Laser for OTC (Over-the-Counter) use K0535</i>	<i>Flash N Go or OTC (Over-the-Counter) use K082298</i>	<i>Palomar Medical Technologies, Inc. ABC Hair removal System for Over-the-Counter (OTC) use K060839</i>
<b>Device Type</b>	Diode laser	diode		Diode laser
<b>Wavelength (nm)</b>	800	800	475 - 1200	810
<b>Fluence (J/cm<sup>2</sup>)</b>	(b)(4)	(b)(4)	5 - 7	3 - 9
<b>Indications</b>	<i>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 growth defined as a long-term, stable reduction in hair counts following a treatment regime</i>	<i>an over the counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatment for Fitzpatrick Skin types I – IV.</i>	<i>an over the counter device intended for hair removal</i>	<i>an over the counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatment for Fitzpatrick Skin types I – IV.</i>
<b>Use</b>	Over the counter (OTC) consumer home use	Over the counter (OTC) consumer home use	Over the counter (OTC) consumer home use	Over the counter (OTC) consumer home use

**V. Labeling**

The firm has provided OTC use instructions (b)(4)

(b)(4)

An OTC device submission should include data which demonstrates that individuals can use the device safely and effectively using the written instructions; in addition the data should demonstrate that individuals can correctly determine that the device is appropriate for their specific use.

**VI. Sterilization/Shelf Life/Reuse**

The *Tria Hair Removal Diode Laser for Over-the-Counter use* is provided non-sterile and is reusable.

**VIII. Software**

(b)(4)

**VII. Performance Testing – Bench**

(b)(4) would not be required to demonstrate SE because of SE regarding indications for use, and device specifications.

**VIII. Performance Testing – Animal**

(b)(4) would not be required to demonstrate SE because of SE regarding indications for use, and device specifications.

**IX. Performance Testing – Clinical**

(b)(4)

(b)(4) FDA has granted 510(k) marketing clearance for other laser devices for hair removal for *Over-the-Counter use* (see K060839, K082298, K053527). The performance data for this submission was forwarded to (b)(4) (b)(4) for his review.

**X. Substantial Equivalence Discussion**

	Yes	No	
1. Is Product A Device	X		If NO = Stop, see 510(k) staff
2. Is Device Subject To 510(k)?	X		If NO = Stop, see 510(k) staff
3. Same Indication Statement?		X	If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		X	If YES = Stop NSE
5. Same Technological Characteristics?	X		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	X		If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
9. Accepted Scientific Methods Exist?			If NO = Stop NSE
10. Performance Data Available?	X		If NO = Request Data
11. Data Demonstrate Equivalence?	X		Final Decision: SE

**XI. Deficiencies:**

**XIV. Contact History:**

(b)(4)

(b)(4)

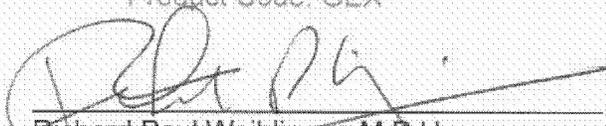
**XV. Recommendation:** I recommend that the submission be found SE

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser Surgical Instrument for use in General and Plastic Surgery and in dermatology

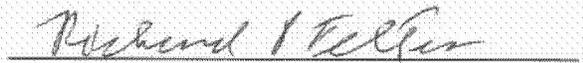
Regulatory Class: Class II

Product Code: GEX



Richard Paul Weiblinger, M.P.H.  
Reviewer, GSDB/DSORD

\_\_\_\_\_ Date



Neil Ogden  
Branch Chief, GSDB/DSORD

19-23-09

\_\_\_\_\_ Date

*Acting*



cc: RWeiblinger ODE/DGRD/GSDB  
Gen. Surge Div. File



*Protecting and Promoting Public Health*

**Weiblinger, Rick**

**From:** Felten, Richard P.  
**Sent:** Tuesday, December 22, 2009 12:35 PM  
**To:** Weiblinger, Rick  
**Subject:** FW: TRIA Beauty TRIA Laser Hair Removal System (K090820)  
**Attachments:** 001\_TRIA Hair Reduction System 510(k) Response - 12.22.09.pdf

Rick:

(b)(4) it looks OK to me. Print it out in color so it is clear and make a note in your review that (b)(4)

Richard

---

**From:** Woodlee, Danielle C. [mailto:dcwoodlee@hhlaw.com]  
**Sent:** Tuesday, December 22, 2009 12:32 PM  
**To:** Felten, Richard P.  
**Cc:** Kahan, Jonathan S.; Smith, John J.  
**Subject:** TRIA Beauty TRIA Laser Hair Removal System (K090820)

Dear Mr. Felten,

This e-mail is in response to your December 18, 2009, e-mail to Jonathan Kahan (below) (b)(4) TRIA Beauty's TRIA Laser Hair Reduction System (K090820). The company appreciates your feedback (b)(4) Please note, this response is being formally filed with the Document Mail Center today.

We trust that the information provided in the attached response is sufficient to address the agency's concerns. If you have any additional questions or concerns, please do not hesitate to contact us. Upon a finding of substantial equivalence, please fax the substantial equivalence letter to Jonathan Kahan's attention at 202-637-5910.

Happy Holidays,

Danielle Woodlee

**From:** Felten, Richard P. [mailto:Richard.Felten@fda.hhs.gov]  
**Sent:** Friday, December 18, 2009 3:37 PM  
**To:** Smith, John J.; Kahan, Jonathan S.  
**Subject:** TRIA K090820

Jonathan:

(b)(4)

If you can get these changes to me on Monday, hopefully I will be able to get to work, we will try to get this out this week.

12/22/2009

DJA X00015

Richard P. Felten  
Center for Devices and Radiological Health  
Office of Device Evaluation  
Division of Surgical, Orthopedic, and Restorative Devices  
General Surgery Devices Branch

DANIELLE WOODLEE, ATTORNEY AT LAW  
HOGAN & HARTSON LLP  
Columbia Square, 555 Thirteenth Street, NW, Washington, DC 20004  
direct +1.202.637.8853 | tel +1.202.637.5600 | fax +1.202.637.5910  
[dcwoodlee@hhlaw.com](mailto:dcwoodlee@hhlaw.com) | <http://www.hhlaw.com>

*Please consider the environment before printing this e-mail.*

---

This electronic message transmission contains information from this law firm which may be confidential or privileged. The information is intended to be for the use of the individual or entity named above. If you are not the intended recipient, be aware that any disclosure, copying, distribution or use of the contents of this information is prohibited.

If you have received this electronic transmission in error, please notify us by telephone (+1-202-637-5600) or by electronic mail ([PostMaster@HHLAW.COM](mailto:PostMaster@HHLAW.COM)) immediately.



















































# COVER SHEET MEMORANDUM

Reviewer Name Richard K. Kibling  
Subject: 510(k) Number 609082d9  
To: The Record

Please list CTS decision code AF

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist [http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0\\_5631/Screening%20Checklist%207%202%2007.doc](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc))
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	<input checked="" type="checkbox"/>	<input type="checkbox"/>
510(k) Summary /510(k) Statement	Attach Summary	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Truthful and Accurate Statement.	Must be present for a Final Decision	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the device Class III?		<input type="checkbox"/>	<input type="checkbox"/>
If yes, does firm include Class III Summary?	Must be present for a Final Decision	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does firm reference standards? (If yes, please attach form from <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )		<input type="checkbox"/>	<input type="checkbox"/>
Is this a combination product? (Please specify category _____, see <a href="http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )		<input type="checkbox"/>	<input type="checkbox"/>
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">http://www.fda.gov/cdrh/ode/guidance/1216.html</a> )		<input type="checkbox"/>	<input type="checkbox"/>
Is this device intended for pediatric use only?		<input type="checkbox"/>	<input type="checkbox"/>
Is this a prescription device? (If both prescription & OTC, check both boxes.)		<input type="checkbox"/>	<input type="checkbox"/>
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		<input type="checkbox"/>	<input type="checkbox"/>
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)		<input type="checkbox"/>	<input type="checkbox"/>
Does this device include an Animal Tissue Source?		<input type="checkbox"/>	<input type="checkbox"/>
All Pediatric Patients age <=21		<input type="checkbox"/>	<input type="checkbox"/>
Neonate/Newborn (Birth to 28 days)		<input type="checkbox"/>	<input type="checkbox"/>
Infant (29 days -< 2 years old)		<input type="checkbox"/>	<input type="checkbox"/>
Child (2 years -< 12 years old)		<input type="checkbox"/>	<input type="checkbox"/>
Adolescent (12 years -< 18 years old)		<input type="checkbox"/>	<input type="checkbox"/>
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age >= 21 (different device design or testing, different protocol procedures, etc.)		<input type="checkbox"/>	<input type="checkbox"/>

DJA X00072

Transitional Adolescent B (18 ≤ 21; No special considerations compared to adults ⇒ 21 years old)			
technology			
is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <a href="http://www.fda.gov/cdrh/comp/guidance/169.html">http://www.fda.gov/cdrh/comp/guidance/169.html</a> )		Contact OC.	

Regulation Number

Class\*

Product Code

*II*

*OHT*

(\*If unclassified, see 510(k) Staff)

Additional Product Codes:

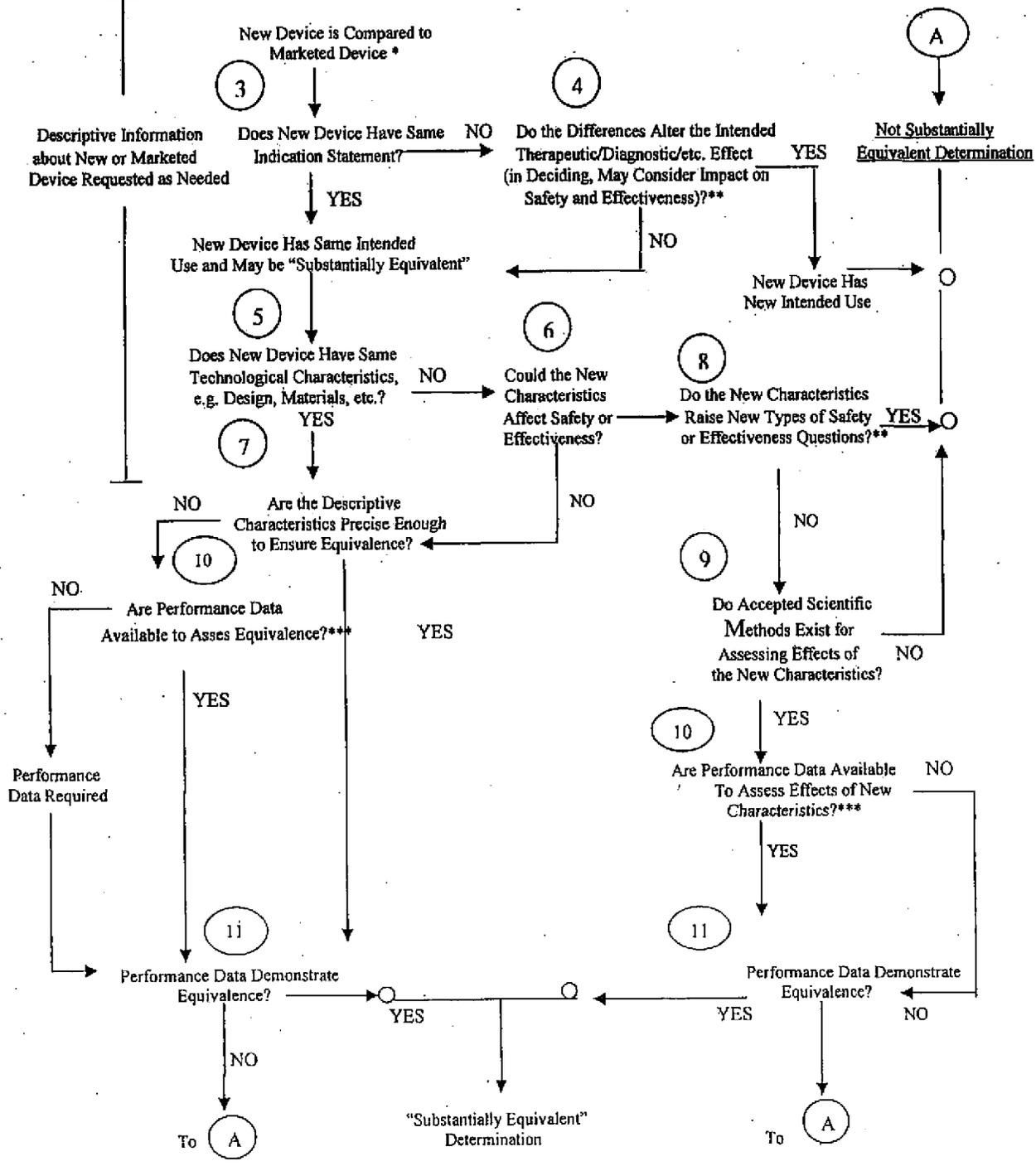
Review:

*for Mark J. Millan* *GSDB* *11/27/09*  
 (Branch Chief) (Branch Code) (Date)

Final Review:

*Mark J. Millan* *11/27/09*  
 (Division Director) (Date)

### 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- ❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- ❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.



Food and Drug Administration  
Office of Device Evaluation  
9200 Corporate Boulevard  
Rockville, MD 20850

**Premarket Notification [510(k)] Review  
Traditional/Abbreviated**

**K090820/S1\_\_\_\_\_**

Date: November 27, 2009

To: The Record

From: Richard P. Felten

Office: ODE

Division: DSORD

510(k) Holder: TRIA Beauty, Inc. (Spectragenics)

Device Name: TRIA Hair Reduction System

Contact: Jonathan Kahn, Hogan & Hartson LLP

Phone: 202-637-5794

Fax: 202-637-5910

Email: JSKahn@hhlaw.com

**I. Purpose and Submission Summary**

The 510(k) holder would like to introduce TRIA Hair Reduction System into interstate commerce.

**II. Administrative Requirements**

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form			X

**III. Device Description**

See previous review by Richard Weiblinger

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?	X		
Are "cleaning" instructions included for the end user?			

**IV. Indications for Use**

Company is requesting expansion of the original OTC indication for use to now include a new indication for use which would be "permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime".

**V. Predicate Device Comparison**

See previous review

**VI. Labeling**

(b)(4)

**VII. Sterilization/Shelf Life/Reuse**

N/A

**VIII. Biocompatibility**

Is acceptable, see previous review.

**IX. Software**

(b)(4)

Version:		
Level of Concern:		
	Yes	No
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

**X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety**

(b)(4)

**XI. Performance Testing – Bench**

N/A

**XII. Performance Testing – Animal**

N/A

**XIII. Performance Testing – Clinical**

Clinical data has been provided and was reviewed in original submittal.

**XIV. Substantial Equivalence Discussion**

	Yes	No
1. Same Indication Statement?		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		If YES = Stop NSE
3. Same Technological Characteristics?		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		If YES = Stop NSE
7. Accepted Scientific Methods Exist?		If NO = Stop NSE
8. Performance Data Available?		If NO = Request Data
9. Data Demonstrate Equivalence?		Final Decision:

**XV. Deficiencies**

1. (b)(4)

2. The user manual needs to have a summary of the actual clinical study and the results of the study added to the manual. This can go into the section that discusses the benefits of using the TRIA that were identified in a clinical study.

(b)(4)

3. Need to check the placement of the Skin Sensor on page 3-13, number 6. (b)(4)

(b)(4)

**XVI. Contact History**

Mr. Jonathan Kahn, Hogan & Hartson was contacted by telephone on November 25, 2009 and informed about the above issues. It was agreed that an electronic copy of these would be forwarded to him on November 27, 2009.

**XVII. Recommendation HOLD**

*Richard P. Telfer*

\_\_\_\_\_  
Reviewer

*11-27-09*

\_\_\_\_\_  
Date

\_\_\_\_\_  
Branch Chief

\_\_\_\_\_  
Date

November 27, 2009

Review of K090820/S1

Submitted by Hogan & Hartson  
for TRIA Beauty Inc.

Reviewed by Richard P. Felten, DSORD, GSDB

*Richard P. Felten*

(b)(4)

(b)(4) The company already has clearance for this device for over-the-counter (OTC) sales for the temporary removal of unwanted hair when used as an adjunct to shaving. This 510(k) was submitted to request an expansion of the indication for use to now include the indication for use of "permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime". (b)(4)

(b)(4)

(b)(4)

1. (b)(4)

2. The user manual needs to have a summary of the actual clinical study and the results of the study added to the manual. This can go into the section that discusses the benefits of using the TRIA that were identified in a clinical study. (b)(4)

(b)(4)

3. Need to check the placement of the Skin Sensor on page 3-13, number 6.

(b)(4)

At this time I recommend that this supplement be placed on HOLD.

DJA X00079

**Felten, Richard P.**

---

**From:** Felten, Richard P.  
**Sent:** Friday, November 27, 2009 8:25 AM  
**To:** 'Jonathan S. Kahan'  
**Subject:** TRIA

Jonathan:

I have attached the deficiencies that need to be addressed (b)(4)

(b)(4)

1. (b)(4)
2. The user manual needs to have a summary of the actual clinical study and the results of the study added to the manual. This can go into the section that discusses the benefits of using the TRIA that were identified in a clinical study. (b)(4)  
(b)(4)
3. Need to check the placement of the Skin Sensor on page 3-13, number 6. (b)(4)  
(b)(4)

If you have any questions I should be here most of the day and I do plan on coming in for some time on Monday morning before taking off on vacation for the rest of the week. I am assuming I will have e-mail access in Las Vegas and do read my e-mails on a daily basis.

Richard P. Felten  
Center for Devices and Radiological Health  
Office of Device Evaluation  
Division of Surgical, Orthopedic, and Restorative Devices  
General Surgery Devices Branch

**COVER SHEET MEMORANDUM**

**From:** Reviewer Name RICHARD WEIBLINGER  
**Subject:** 510(k) Number 1090820  
**To:** The Record

- Please list CTS decision code A.I.
- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist [http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0\\_5631/Screening%20Checklist%207%202%2007.doc](http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc))
  - Hold (Additional Information or Telephone Hold)
  - Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	<input checked="" type="checkbox"/>	<input type="checkbox"/>
510(k) Summary /510(k) Statement	Attach Summary	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Truthful and Accurate Statement.	Must be present for a Final Decision	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the device Class III?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, does firm include Class III Summary?	Must be present for a Final Decision	<input type="checkbox"/>	<input type="checkbox"/>
Does firm reference standards? (If yes, please attach form from <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )		<input type="checkbox"/>	<input type="checkbox"/>
Is this a combination product? (Please specify category _____, see <a href="http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )		<input type="checkbox"/>	<input type="checkbox"/>
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">http://www.fda.gov/cdrh/ode/guidance/1216.html</a> )		<input type="checkbox"/>	<input type="checkbox"/>
Is this device intended for pediatric use only?		<input type="checkbox"/>	<input type="checkbox"/>
Is this a prescription device? (If both prescription & OTC, check both boxes.)		<input type="checkbox"/>	<input type="checkbox"/>
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of <a href="http://ClinicalTrials.gov">ClinicalTrials.gov</a> Data Bank? (If not, then applicant must be contacted to obtain completed form.)		<input type="checkbox"/>	<input type="checkbox"/>
Does this device include an Animal Tissue Source?		<input type="checkbox"/>	<input type="checkbox"/>
All Pediatric Patients age <= 21		<input type="checkbox"/>	<input type="checkbox"/>
Neonate/Newborn (Birth to 28 days)		<input type="checkbox"/>	<input type="checkbox"/>
Infant (29 days - < 2 years old)		<input type="checkbox"/>	<input type="checkbox"/>
Child (2 years - < 12 years old)		<input type="checkbox"/>	<input type="checkbox"/>
Adolescent (12 years - < 18 years old)		<input type="checkbox"/>	<input type="checkbox"/>
Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)		<input type="checkbox"/>	<input type="checkbox"/>
Transitional Adolescent B (18 - <= 21; No special considerations compared to adults => 21 years old)		<input type="checkbox"/>	<input type="checkbox"/>
anotechnology		<input type="checkbox"/>	<input type="checkbox"/>

DJA X00114

DJA X00115

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, <a href="http://www.fda.gov/cdrh/osb/guidance/316.html">http://www.fda.gov/cdrh/osb/guidance/316.html</a> )	Contact OSB.		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <a href="http://www.fda.gov/cdrh/comp/guidance/169.html">http://www.fda.gov/cdrh/comp/guidance/169.html</a> )	Contact OC.		

Regulation Number \_\_\_\_\_ Class\* Class II Product Code GEX

(\*If unclassified, see 510(k) Staff)

Additional Product Codes: \_\_\_\_\_

Review: Neil R. D. Gula GSDB 5/21/09  
 (Branch Chief) (Branch Code) (Date)

Final Review: \_\_\_\_\_  
 (Division Director) (Date)



Food and Drug Administration  
Office of Device Evaluation  
9200 Corporate Boulevard  
Rockville, MD 20850

Premarket Notification [510(k)] Review  
Traditional/Abbreviated

K090820

Date: 5/22/09  
To: The Record  
From: Richard Paul Weiblinger, M.P.H.

Office: ODE  
Division: DGRND

*Review of K090820  
Original*

510(k) Holder: Spectragenics, Inc.  
Device Name: Tria Hair Removal Laser for Over the Counter use  
Contact: Tobin Island  
Phone: 925-701-2554  
Email:

**I. Purpose and Submission Summary**

The firm has submitted a premarket notification which is a marketing clearance request with the purpose of this submission and the intent of the sponsor being to introduce into interstate commerce a new device the *Tria Hair Removal Diode Laser for Over-the-Counter use (OTC) which is intended to be used as a patient self-use device.*

The subject device is the 4<sup>th</sup> laser for *Over-the-Counter use (OTC) which is intended to be used as a patient self-use device for laser hair removal.* FDA previously has granted 510(k) marketing clearance for other laser devices for laser hair removal *Over-the-Counter use (see K082298, K060839, and K053527).*

*The device is a compact, portable, self-contained system which emits light at a wavelength of 800 nm.* (b)(4)

(b)(4)

**II. Administrative Requirements**

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	x		
Truthful and Accuracy Statement	x		
510(k) Summary or 510(k) Statement	x		
Standards Form #3654 <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a>	x		
Clinical Trials Form <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf</a>	x		

**III. Device Description**

The device is the *Tria Hair Removal Diode Laser for Over-the-Counter use (non-prescription)*.

(b)(4)

(b)(4) The firm has provided a comparison table which provides device specification comparisons.

	Yes	No	N/A
Is the device life-supporting or life sustaining?		x	
Is the device an implant (implanted longer than 30 days)?		x	
Does the device design use software?	x		
Is the device sterile?		x	
Is the device reusable (not reprocessed single use)?			
Are validated "cleaning" instructions included for the end user?	x		

**IV. Indications for Use**

Subject device: The *Tria Hair Removal system (K090820)* is an over the counter device (b)(4)

(b)(4)

Predicate device: The Spectrogenics *Hair Removal (K053527)* system is an over the counter device intended for removal of unwanted hair.

(b)(4)

(b)(4)



<b>Device Characteristic</b>	<i>Spectragenics, Inc. Tria Hair Removal Diode Laser for OTC (Over-the-Counter) use K090820</i>	<i>Spectragenics, Inc. Spectra™ Hair Removal Diode Laser for OTC (Over-the-Counter) use K0535</i>	<i>Flash N Go or OTC (Over-the-Counter) use K082298</i>	<i>Palomar Medical Technologies, Inc. ABC Hair removal System for Over-the-Counter (OTC) use K060839</i>
<b>Device Type</b>	Diode laser	diode		Diode laser
<b>Wavelength (nm)</b>	800	800	475 - 1200	810
<b>Fluence (J/cm<sup>2</sup>)</b>	(b)(4)	(b)(4)	5 - 7	3 - 9
<b>Indications</b>	(b)(4)	<i>an over the counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatment for Fitzpatrick Skin types I – IV.</i>	<i>an over the counter device intended for hair removal</i>	<i>an over the counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatment for Fitzpatrick Skin types I – IV.</i>
<b>Use</b>	Over the counter (OTC) consumer home use	Over the counter (OTC) consumer home use	Over the counter (OTC) consumer home use	Over the counter (OTC) consumer home use

**VI. Labeling**

The firm has provided OTC use instructions (b)(4)

(b)(4)

An OTC device submission should include data which demonstrates that individuals can use the device safely and effectively using the written instructions; in addition the data should demonstrate that individuals can correctly determine that the device is appropriate for their specific use.

**VII. Sterilization/Shelf Life/Reuse**

The *Tria Hair Removal Diode Laser for Over-the-Counter use* is provided non-sterile and is reusable.

**IX. Software**

(b)(4)

**X. Performance Testing – Clinical**

(b)(4)

FDA has granted 510(k) marketing clearance for other laser devices for hair removal for *Over-the-Counter use* (see K060839, K082298, K053527). (b)(4)

(b)(4)

**XI. Substantial Equivalence Discussion**

**Predicate Devices:** The designated predicate devices are as described in the following table:

510 (k) Number	Manufacturer	Device
K060839	Palomar Medical Technologies, Inc.	<i>ABC Hair removal System for Over- the- Counter (OTC) use</i>
K053527	<i>Spectgragenics, Inc.</i>	<i>Spectra Hair Removal Laser for OTC use</i>
K082298	Home Skinovations, Ltd.	<i>Flash n Go for OTC use</i>

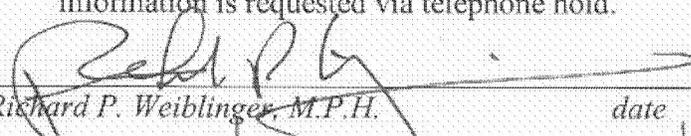
**XII. Contact History** (b)(4)

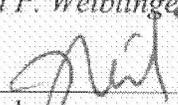
(b)(4)

(b)(4)

**XIII. Recommendation**

There is inadequate information to determine substantial equivalence. Additional information is requested via telephone hold.

  
Richard P. Weiblinger, M.P.H. date

 I concur with AT.  
Neil Ogden date 5/21/09  
Chief, General Surgical Devices Branch, DGRD

Concur  
 Do Not Concur



cc: RWeiblinger ODE/DGRD/GSDB  
Gen. Surge Devices Branch



*Protecting and Promoting Public Health*

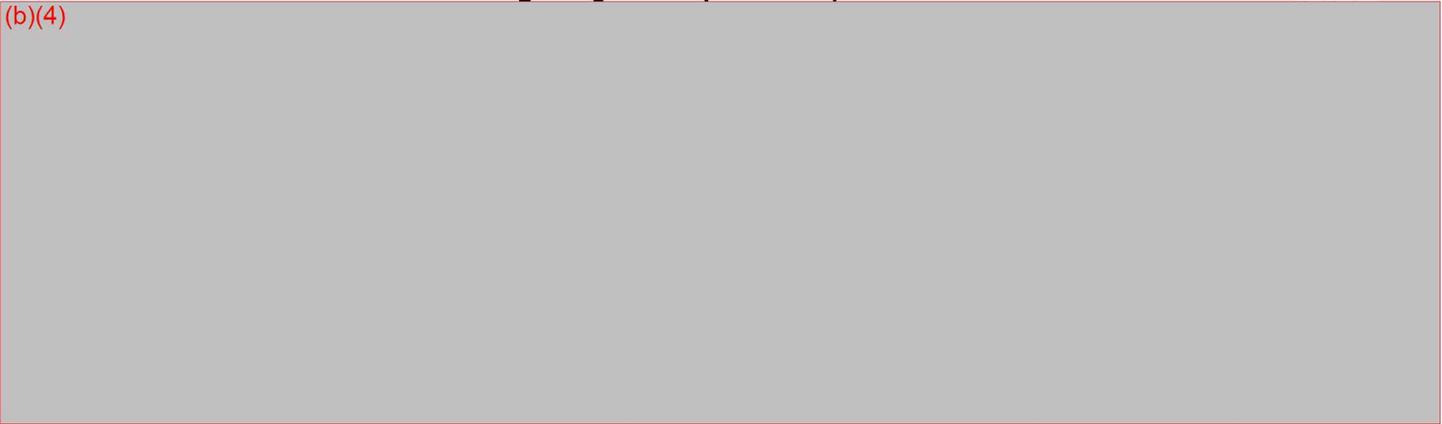
**Weiblinger, Rick**

---

**From:** Felten, Richard P.  
**Sent:** Tuesday, May 19, 2009 2:15 PM  
**:** Ogden, Neil; Weiblinger, Rick  
**Subject:** Spectragenics

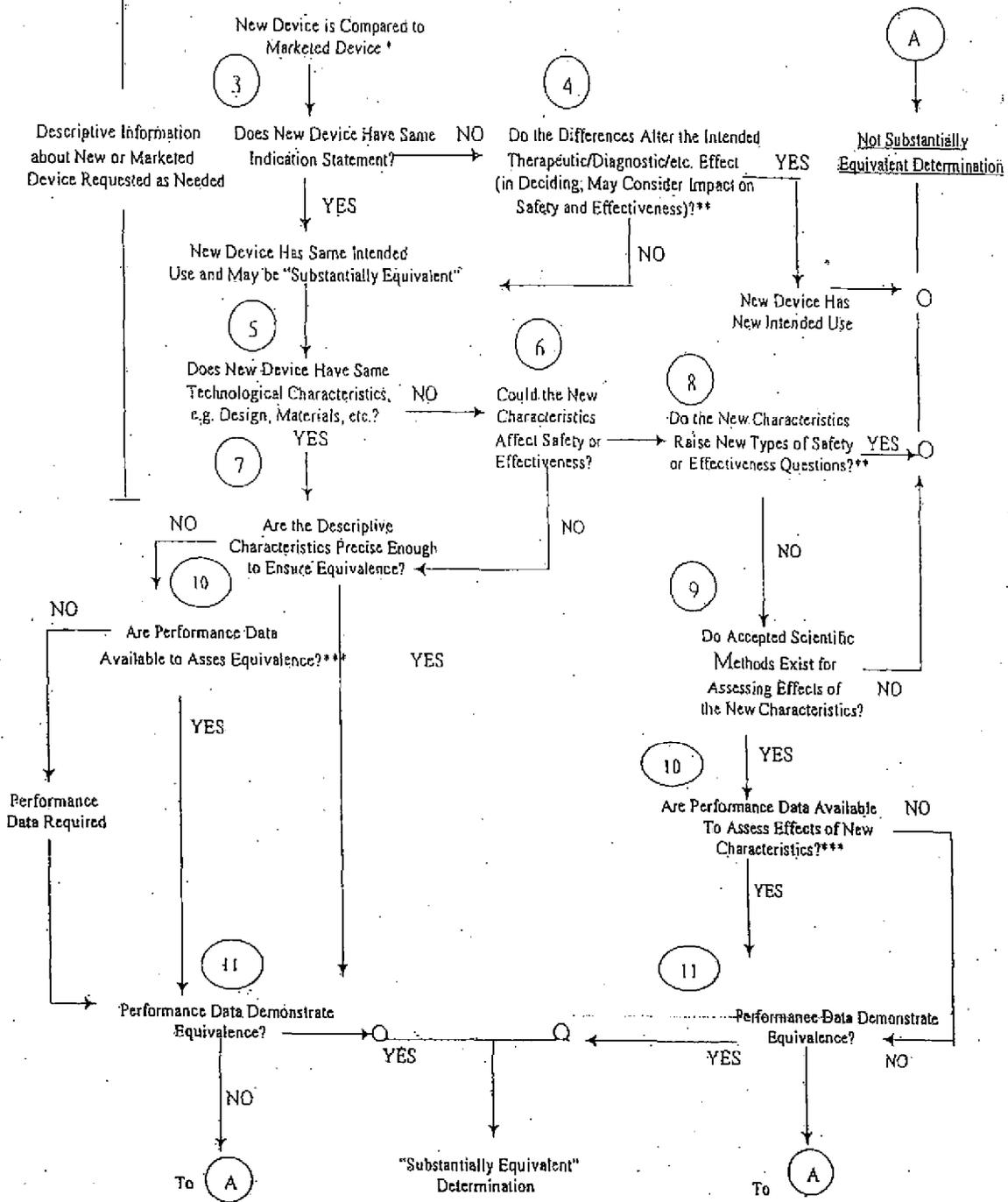
I think we need to discuss several issues regarding their request for expansion of their OTC indications for use (b)(4)

(b)(4)



Richard

### 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- ❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- ❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DJA X00082

K090820/S1

# HOGAN & HARTSON

Hogan & Hartson LLP  
Columbia Square  
555 Thirteenth Street, NW  
Washington, DC 20004  
+1.202.637.5600 Tel  
+1.202.637.5910 Fax

[www.hhlaw.com](http://www.hhlaw.com)

November 18, 2009

FDA CDRH DMC

NOV 18 2009

Jonathan S. Kahan  
Partner  
1.202.637.5794  
JSKahan@hhlaw.com

Received

**BY HAND DELIVERY**

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Attn: Richard Weiblinger (Room 1426)

**Re: Follow-up to Conference Call Regarding the 510(k) Notice for the TRIA Hair Reduction System (K090820)**

Dear Mr. Weiblinger:

On behalf of our client, TRIA Beauty, Inc. (“TRIA Beauty” or the “company”), we are writing to provide the U.S. Food and Drug Administration (“FDA” or the “agency”) with (b)(4)

(b)(4)

The 510(k) notice for this device was filed on March 25, 2009. (b)(4)

(b)(4)

(b)(4) The company subsequently received a letter from FDA placing the submission on hold.

K56

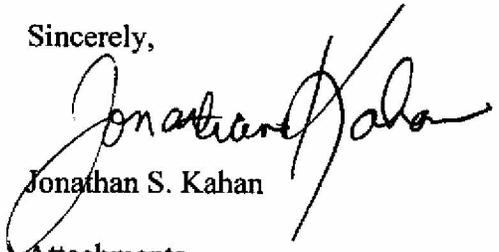
(b)(4)



\* \* \*

We trust that this response fully addresses FDA's concerns as outlined in the May 21, 2009, teleconference so as to allow a determination of substantial equivalence to the claimed predicate devices. If you have any questions concerning this response, please contact me at the above number or John Smith at (202) 637-3638. Upon a finding of substantial equivalence, please fax the clearance letter to my attention at (202) 637-5910.

Sincerely,



Jonathan S. Kahan

Attachments

- cc: Tobin Island, Ph.D., TRIA Beauty, Inc.
- Lisa Parr, Pharm.D., TRIA Beauty, Inc.
- John J. Smith, M.D., J.D., Hogan & Hartson, LLP
- Lina R. Kontos, Hogan & Hartson, LLP

**Indications for Use Statement**

510(k) Number (if known): K090820

Device Name: TRIA

Indications for Use:

(b)(4)

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)

**Indications for Use Statement**

510(k) Number (if known): K090820

Device Name: TRIA

Indications for Use:

(b)(4)

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)

**510(k) SUMMARY**

**TRIA Hair Removal Laser System**

**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  
Facsimile: 925-701-2598  
Contact Person: Tobin C. Island, Ph.D.  
Date Prepared: March 4, 2009

**Name of Device and Name/Address of Sponsor**

TRIA Hair Removal Laser System  
TRIA Beauty, Inc.  
5880 W. Las Positas Blvd., Suite 52  
Pleasanton, CA 94588-8552

**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**

SpectraGenics Spectra Hair Removal Laser System (K053527)  
Star Medical Technologies LightSheer Pulsed Diode Array Laser System (K982940)  
Home Skinovations Flash N' Go (K082298)

**Intended Use / Indications for Use**

(b)(4)

**Technological Characteristics**

(b)(4)  
(b)(4) The TRIA Hair Removal Laser is a semiconductor diode laser system that delivers infrared light at a wavelength of nominally 800 nm. (b)(4)  
(b)(4)

**Performance Data**

Clinical trials have been conducted to demonstrate the safety and efficacy of the TRIA  
(b)(4) The study results indicate that the TRIA (b)(4)  
(b)(4)

**Substantial Equivalence**

The TRIA is as safe and effective as the predicate devices. The TRIA has the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate devices. Minor differences between the TRIA 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 the TRIA is as safe and effective as its predicate devices for the stated indications. Thus, the TRIA is substantially equivalent.











































## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

## Public Health Service

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

December 08, 2009

SPECTRAGENICS, INC.  
5880 W. LAS POSITAS BLVD SUITE 52  
PLEASANTON, CALIFORNIA 94588-8522  
UNITED STATES  
ATTN: TOBIN C. ISLAND

510k Number: K090820

Product: TRIA HAIR REMOVAL LASER

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

K090820/8002

DJA X00041

# HOGAN & HARTSON

Hogan & Hartson LLP  
Columbia Square  
555 Thirteenth Street, NW  
Washington, DC 20004  
+1.202.637.5600 tel  
+1.202.637.5910 Fax

www.hhlaw.com

December 7, 2009

FDA CDRH DMC

DEC 07 2009

Jonathan S. Kahan  
Partner  
+1.202.637.5794  
JSKahan@hhlaw.com

*By Messenger*

Received

K-63

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Attn: Richard Felten (Room 1436)

**Re: Premarket Notification for TRIA Beauty's TRIA Laser Hair Removal System (K090820)**

Dear Mr. Felten:

We are writing in response to the Food and Drug Administration's ("FDA" or "the Agency") November 27, 2009, e-mail requesting additional information concerning the 510(k) notice for the TRIA Beauty ("TRIA Beauty" or "the Company") TRIA Laser Hair Removal System (K090820) ("TRIA" or "the device"). In addition to the Company's responses, which are outlined below, (b)(4)

(b)(4)

(b)(4) update the company name to TRIA Beauty.

(b)(4)

For the Agency's ease of review, the Company has reproduced the items from the Agency's November 27 e-mail in italics below, followed by the Company's response to each.

(b)(4)



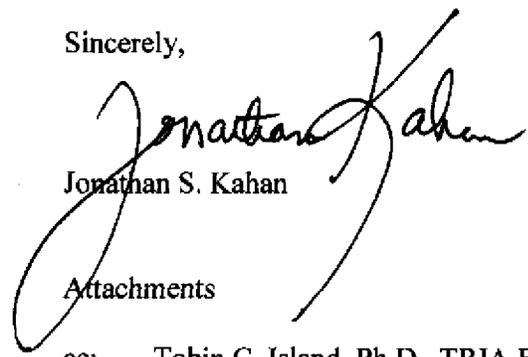
(b)(4)



\* \* \*

The Company believes that this response fully addresses the issues raised in FDA's November 27 e-mail. We trust that the information provided is sufficient for the Agency to find the TRIA Laser Hair Removal System substantially equivalent to its predicate devices for the listed indication. If you have any further questions, please contact me at the number above or John Smith at 202-637-3638. Upon clearance of the device, please fax the substantial equivalence letter to me at 202-637-5910.

Sincerely,



Jonathan S. Kahan

Attachments

- cc: Tobin C. Island, Ph.D., TRIA Beauty
- Lisa D. Parr, Pharm.D., TRIA Beauty
- John J. Smith, M.D., J.D., Hogan & Hartson, LLP
- Danielle C. Woodlee, Hogan & Hartson, LLP

**Indications for Use Statement**

**510(k) Number (if known):** K090820

**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.

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)

Page \_\_\_ of \_\_\_

**TRIA Laser Hair Removal System (TRIA)**

**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  
Facsimile: 925-701-2598  
Contact Person: Lisa D. Parr, Pharm.D.  
Date Prepared: December 7, 2009

**Name of Device and Name/Address of Sponsor**

TRIA Laser Hair Removal System (TRIA)  
TRIA Beauty, Inc.  
5880 W. Las Positas Blvd., Suite 52  
Pleasanton, CA 94588-8552

**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**

SpectraGenics Spectra Hair Removal Laser System (K053527)  
Star Medical Technologies LightSheer Pulsed Diode Array Laser System (K982940)  
Home Skinovations Flash N' Go (K082298)

**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.

**Technological Characteristics**

TRIA is a semiconductor diode laser system that delivers infrared light at a wavelength of nominally 800 nm.

**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**

TRIA has the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate devices. Any minor differences between the TRIA 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 TRIA is as safe and effective as its predicate devices for the stated indications. Thus, TRIA is substantially equivalent.











































K090820/5002

# HOGAN & HARTSON

Hogan & Hartson LLP  
Columbia Square  
555 Thirteenth Street, NW  
Washington, DC 20004  
+1.202.637.5600 Tel  
+1.202.637.5910 Fax

www.hhlaw.com

December 7, 2009

DEC 07 2009

Jonathan S. Kahan  
Partner  
+1.202.637.5794  
JSKahan@hhlaw.com

By Messenger

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

K-63

Attn: Richard Felten (Room 1436)

Re: **Premarket Notification for TRIA Beauty's TRIA Laser Hair Removal System (K090820)**

Dear Mr. Felten:

We are writing in response to the Food and Drug Administration's ("FDA" or "the Agency") November 27, 2009, e-mail requesting additional information concerning the 510(k) notice for the TRIA Beauty ("TRIA Beauty" or "the Company") TRIA Laser Hair Removal System (K090820) ("TRIA" or "the device"). In addition to the Company's responses, which are outlined below, (b)(4)

(b)(4)

(b)(4) update the company name to TRIA Beauty.

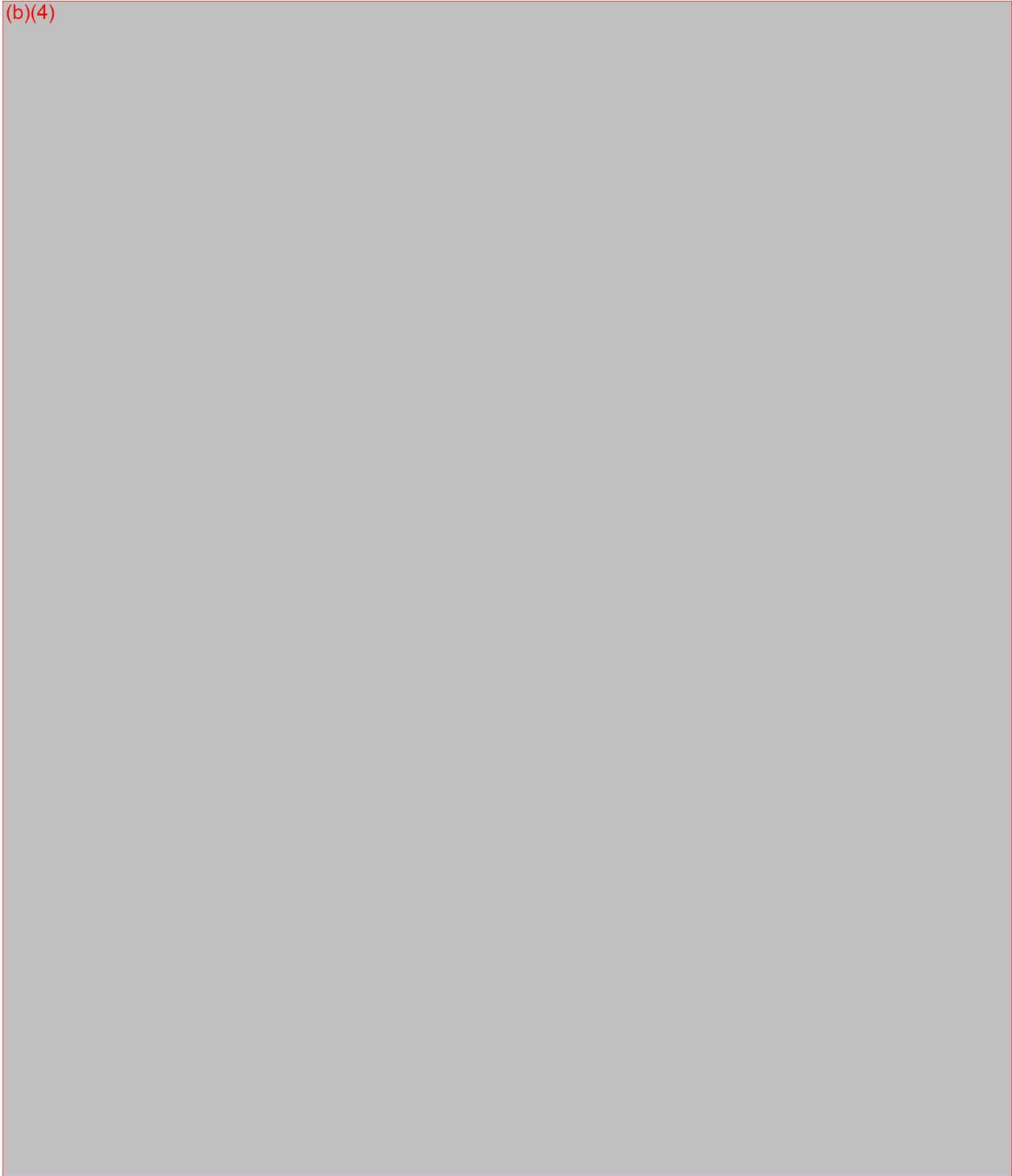
(b)(4)

For the Agency's ease of review, the Company has reproduced the items from the Agency's November 27 e-mail in italics below, followed by the Company's response to each.

(b)(4)



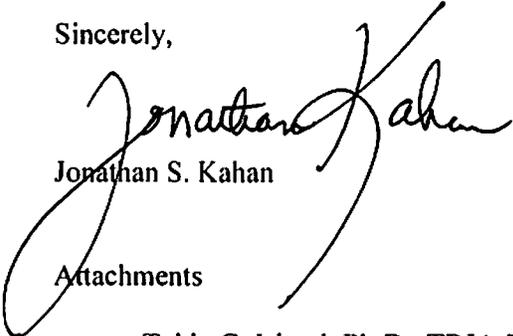
(b)(4)



\* \* \*

The Company believes that this response fully addresses the issues raised in FDA's November 27 e-mail. We trust that the information provided is sufficient for the Agency to find the TRIA Laser Hair Removal System substantially equivalent to its predicate devices for the listed indication. If you have any further questions, please contact me at the number above or John Smith at 202-637-3638. Upon clearance of the device, please fax the substantial equivalence letter to me at 202-637-5910.

Sincerely,



Jonathan S. Kahan

Attachments

cc: Tobin C. Island, Ph.D., TRIA Beauty  
Lisa D. Parr, Pharm.D., TRIA Beauty  
John J. Smith, M.D., J.D., Hogan & Hartson, LLP  
Danielle C. Woodlee, Hogan & Hartson, LLP

# HOGAN & HARTSON

Hogan & Hartson LLP  
Columbia Square  
555 Thirteenth Street, NW  
Washington, DC 20004  
+1.202.637.5600 **Tel**  
+1.202.637.5910 **Fax**

[www.hhlaw.com](http://www.hhlaw.com)

December 7, 2009

Jonathan S. Kahan  
Partner  
+1.202.637.5794  
JSKahan@hhlaw.com

*By Messenger*

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Attn: Richard Felten (Room 1436)

**Re: Premarket Notification for TRIA Beauty's TRIA Laser Hair Removal System (K090820)**

Dear Mr. Felten:

We are writing in response to the Food and Drug Administration's ("FDA" or "the Agency") November 27, 2009, e-mail requesting additional information concerning the 510(k) notice for the TRIA Beauty ("TRIA Beauty" or "the Company") TRIA Laser Hair Removal System (K090820) ("TRIA" or "the device"). In addition to the Company's responses, which are outlined below, (b)(4)

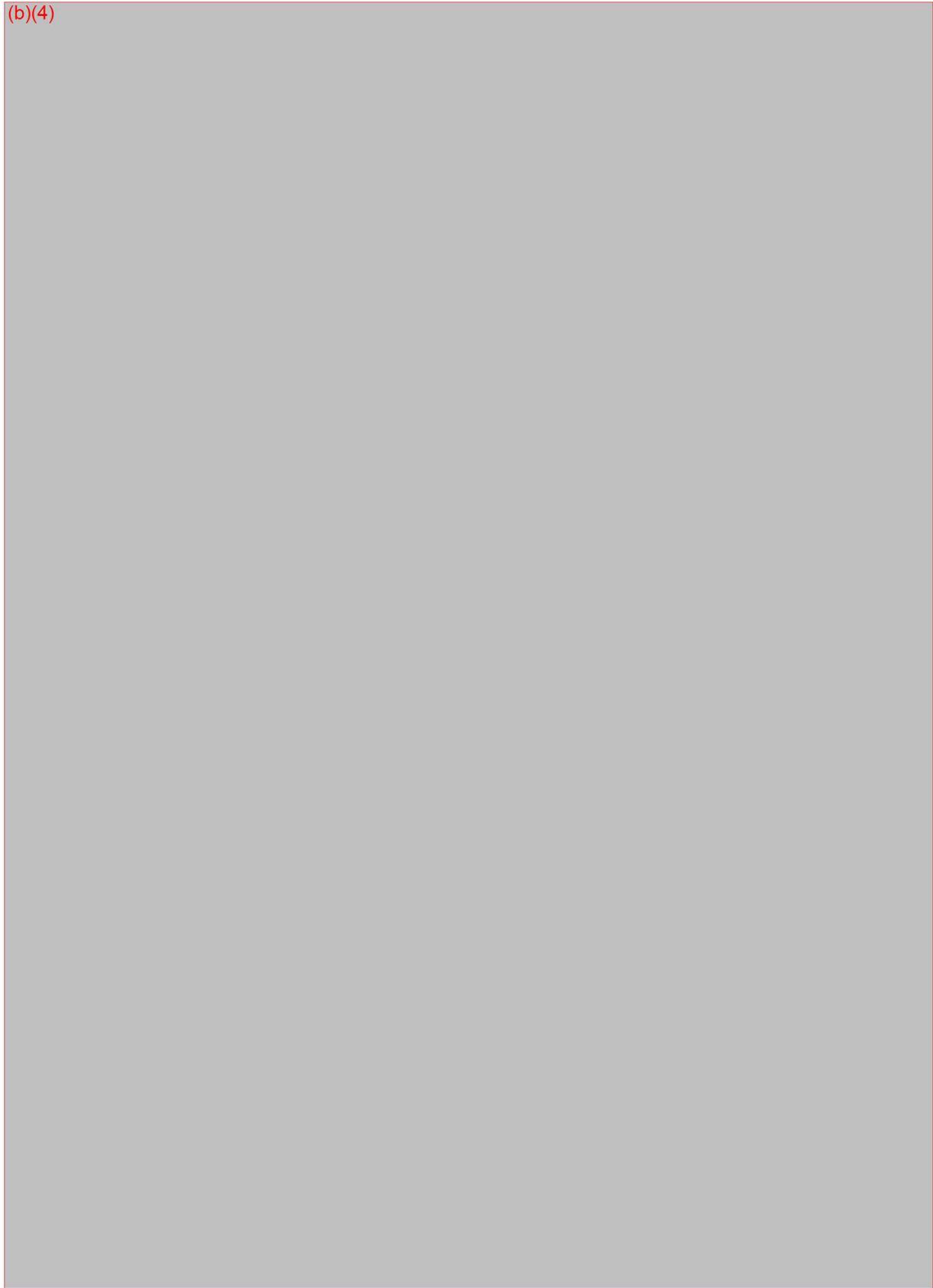
(b)(4)

(b)(4) update the company name to TRIA Beauty.

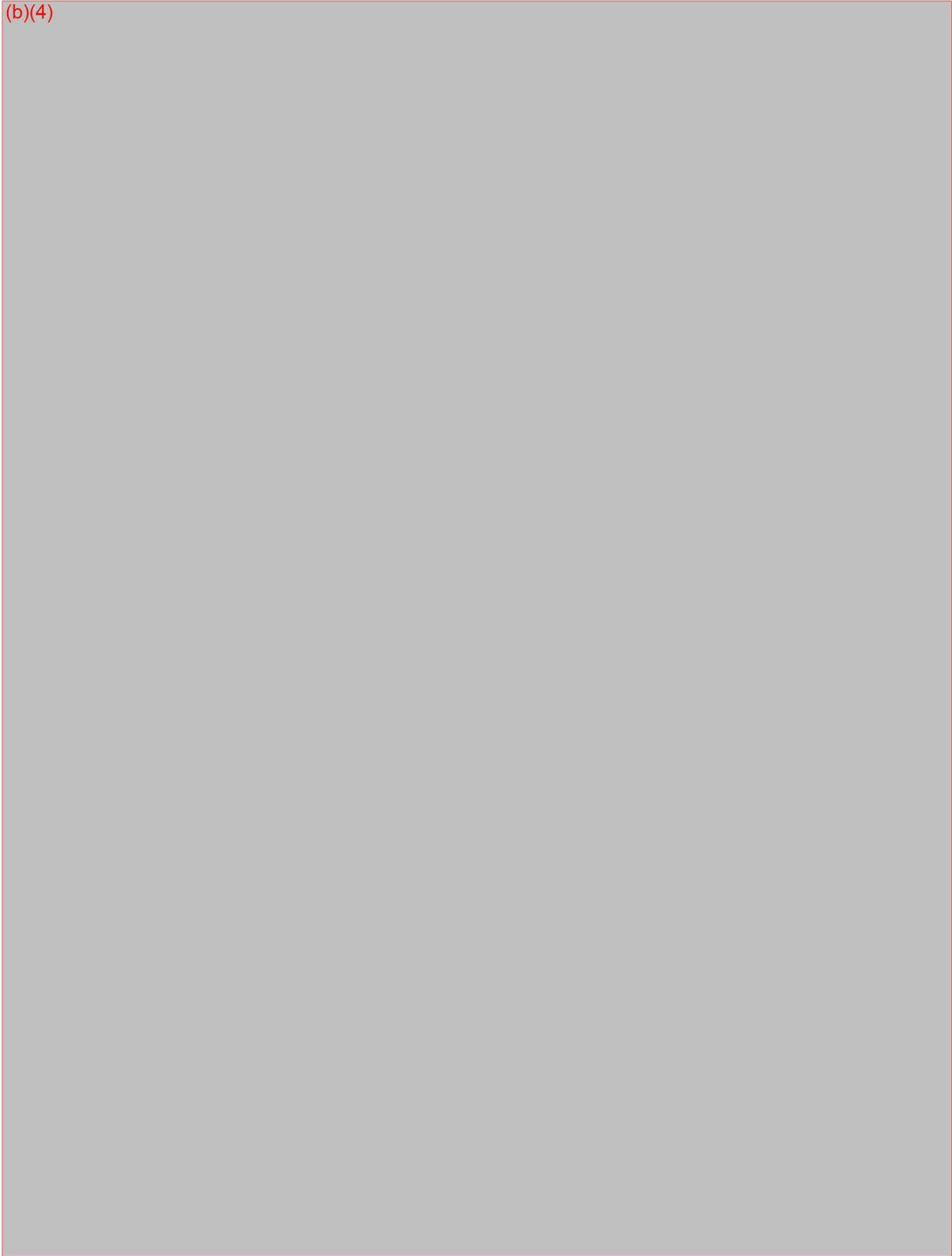
(b)(4)

For the Agency's ease of review, the Company has reproduced the items from the Agency's November 27 e-mail in italics below, followed by the Company's response to each.

(b)(4)



(b)(4)



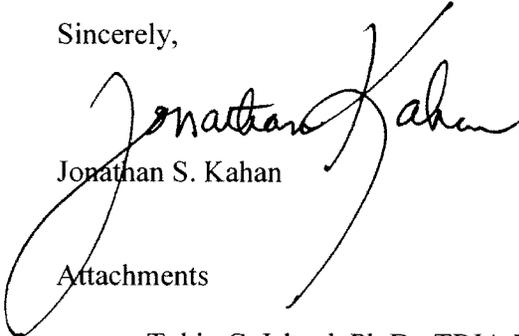
\*

\*

\*

The Company believes that this response fully addresses the issues raised in FDA's November 27 e-mail. We trust that the information provided is sufficient for the Agency to find the TRIA Laser Hair Removal System substantially equivalent to its predicate devices for the listed indication. If you have any further questions, please contact me at the number above or John Smith at 202-637-3638. Upon clearance of the device, please fax the substantial equivalence letter to me at 202-637-5910.

Sincerely,



Jonathan S. Kahan

Attachments

cc: Tobin C. Island, Ph.D., TRIA Beauty  
Lisa D. Parr, Pharm.D., TRIA Beauty  
John J. Smith, M.D., J.D., Hogan & Hartson, LLP  
Danielle C. Woodlee, Hogan & Hartson, LLP

## Indications for Use Statement

**510(k) Number (if known):** K090820

**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.

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)

Page \_\_\_ of \_\_\_

## **TRIA Laser Hair Removal System (TRIA)**

### **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  
Facsimile: 925-701-2598  
Contact Person: Lisa D. Parr, Pharm.D.  
Date Prepared: December 7, 2009

### **Name of Device and Name/Address of Sponsor**

TRIA Laser Hair Removal System (TRIA)  
TRIA Beauty, Inc.  
5880 W. Las Positas Blvd., Suite 52  
Pleasanton, CA 94588-8552

### **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**

SpectraGenics Spectra Hair Removal Laser System (K053527)  
Star Medical Technologies LightSheer Pulsed Diode Array Laser System (K982940)  
Home Skinovations Flash N' Go (K082298)

## **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.

## **Technological Characteristics**

TRIA is a semiconductor diode laser system that delivers infrared light at a wavelength of nominally 800 nm.

## **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**

TRIA has the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate devices. Any minor differences between the TRIA 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 TRIA is as safe and effective as its predicate devices for the stated indications. Thus, TRIA is substantially equivalent.









































