K121515

JUN - 5 2012

SECTION 5: 510(k) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990, 21 CFR 807.92

1. **General Information**

Date of Submission: May 17, 2012

Submitted By: Solta Medical, Inc.
25881 Industrial Blvd
Hayward, CA 94545

Contact Person: Kristine Foss
V.P., Regulatory, Clinical & Quality
510-780-4657 (Direct Phone)
510-780-4857 Fax
kfoss@solta.com

2. **Trade/Proprietary Name of Device:**

Trade Name:	Isolaz® 2 Intense Pulsed Light System
Common Name:	Powered Light Non-laser Surgical Instrument
Regulation Number	878.4810
Product Code:	ONF
Device Panel:	General Surgery/Restorative Devices
Device Classification:	Class II

3. **Legally Marketed Predicate Device for Claimed Equivalence:**

Name: Isolaz® Intense Pulsed Light System
510(k) #: K083730

4. **Device Description**

The Isolaz® 2 System delivers non-coherent 400-1200 nm and 550-1200 nm intense pulsed light via a delivery handpiece utilizing photopneumatic technology. The system consists of a main console and a treatment handpiece. The desired power and delivery time are set by the operator. The modifications made to the device were to reduce and simplify device settings.

5. **Intended Use:**

The Isolaz® 2 System is intended for treatment of mild to moderate acne, including pustular acne, comedonal acne and mild to moderate inflammatory acne (acne vulgaris) in all skin types (Fitzpatrick I-VI).

6. **Technological Characteristics:**
The Isolaz® 2 System is similar to the predicate device in design specification, output energy, and delivery system. They are both intense pulsed light instruments designed to produce light energy for treatment of mild to moderate acne including pustular acne, comedonal acne and inflammatory acne (acne vulgaris) in all skin types (Fitzpatrick I-VI). The modifications to the system console and handpiece hardware and circuitry do not significantly affect the safety or effectiveness of the device. The system was evaluated and found compliant with IEC 60601-1 and 60601-1-4 for electrical safety, IEC 60601-1-2 for EMI/EMC, and ISO 10993-1 for biocompatibility of the treatment tips. Verification and validation data show that the device meets all product specifications.

7. **Performance Data:**
Laboratory and performance tests were executed to ensure that the device functioned as intended and met design specifications. Sufficient data were obtained to show that the device is substantially equivalent to the predicate device and meets safety and effectiveness criteria.

8. **Conclusion:**
By virtue of the design, materials, function and intended use, the Isolaz® 2 Intense Pulsed Light System is as safe, as effective and performs as well as or better than the predicate device. In establishing substantial equivalence to the predicate device, Solta Medical evaluated the indications for use, product specifications, and energy requirements of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 5 2012

Solta Medical
% Ms. Kristine Foss
Vice President, Regulatory , Clinical & Quality
25881 Industrial Boulevard
Hayward, California, 94545

Re: K121515
Trade/Device Name: Isolaz 2 Intense Pulsed Light System
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: ONF
Dated: May 17, 2012
Received: May 22, 2012

Dear Ms. Foss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Robert Nelson

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4:

Indications for Use

510(k) Number (if known): K121515

Device Name: Isolaz® 2 Intense Pulsed Light System

Indications For Use:

Treatment of mild to moderate acne, including pustular acne, comedonal acne and mild to moderate inflammatory acne (acne vulgaris) in all skin types (Fitzpatrick I-VI).

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (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) Number K121515

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

Page 1 of 1