

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

**DATE OF SUBMISSION**

September 7, 2010

K101490

**REGULATORY AUTHORITY**

Safe Medical Devices Act of 1990, 21 CFR 807.92

SEP 08 2010

**COMPANY NAME/CONTACT**

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**NAME OF DEVICE**

Trade Name:	<u>Fraxel re:store® Dual Laser System and Accessories</u>
Common Name:	Laser Surgical Instrument
Regulation Number	878.4810
Product code:	GEX
Device Panel:	General Surgery/Restorative Devices
Device Classification:	Class II

**LEGALLY MARKETED PREDICATE DEVICES**

Name: Fraxel re:store Laser System and Accessories  
510(k) #: K060310

Name: Fraxel re:store® Dual Laser System and Accessories  
510(k) #: K091420

## **DEVICE DESCRIPTION**

The Fraxel re:store® Dual Laser System consists of a 1550 nm laser source and a 1927 nm laser source with fiber delivery and control by an embedded processor for use in dermatological procedures. The laser system uses scanning and focusing optics to deliver a controlled pattern of thermal energy to the epidermis and dermis. Device accessories include tip kits and pre-treatment solution.

## **INDICATION FOR USE STATEMENT**

Indications for use:

1550 nm: The Fraxel re:store® Dual 1550 nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue, as well as for skin resurfacing procedures. It also indicated for treatment of dyschromia and cutaneous lesions, such as, but not limited to lentigos (age spots), solar lentigos (sun spots), actinic keratosis, and melasma, and for treatment of periorbital wrinkles, acne scars and surgical scars.

1927 nm: The Fraxel re:store 1927 nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue and the treatment of actinic keratosis.

## **SUBSTANTIAL EQUIVALENCE COMPARISON**

### **Indications for Use**

Substantial equivalence for the Fraxel re:store® Dual Laser System and Accessories is supported by the predicate devices listed in this submission, which have identical or similar indication statements. Histological and clinical performance data confirmed that the Fraxel re:store Dual® Laser System performs as intended and that no new issues of safety and effectiveness are introduced.

### **Technological Characteristics**

Key technological characteristics of the Fraxel re:store® Dual Laser System, such as energy type and operating principle, are identical to the Fraxel re:store® Dual Laser System described in submission K091420. In particular, the 1550 nm and 1927 nm laser sources and delivery systems are identical. Energy is delivered through the same handpiece for both systems. There are no changes in system software or user interface for the Fraxel re:store® Dual Laser System, which is the subject of this submission, and the device of the predicate submission K091420.

## **Pre-clinical and Clinical Studies**

### **Pre-clinical Studies**

Histological analysis of lesion characteristics (depth and width) created by the 1927 nm wavelength laser in pig skin and excised human abdominal tissue (included in the original Fraxel re:store Dual submission K091420) demonstrated the safety of this wavelength in treating the added indication of actinic keratosis.

### **Clinical Studies**

In clinical studies, safety and efficacy of the 1927 nm wavelength in the treatment of actinic keratosis was demonstrated, and side effects were minimal and well tolerated.

## **CONCLUSION**

Based on the evaluation described within, the Fraxel re:store® Dual Laser System is substantially equivalent to the predicate devices currently marketed in accordance with the Federal Food, Drug and Cosmetic Act. Safety and effectiveness were reasonably assured, justifying 510(k) clearance.



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

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

SEP 08 2010

Re: K101490

Trade/Device Name: Fraxel re:store<sup>®</sup> Dual Laser System and Accessories  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser surgical instrument for use in general and  
Plastic surgery and in dermatology  
Regulatory Class: Class II  
Product Code: ONG  
Dated: August 19, 2010  
Received: August 23, 2010

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.

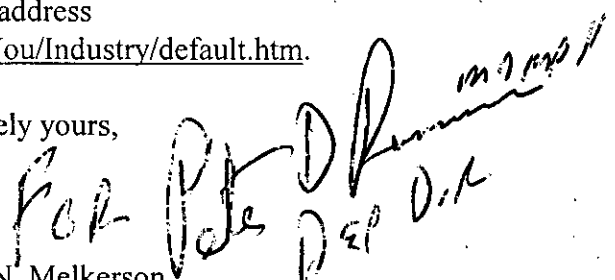
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

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

K101490

SEP 08 2010

510(k) Number K101490:

Device Name: Fraxel re:store® Dual Laser System and Accessories

## Indications for use:

1550 nm: The Fraxel re:store 1550 nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue, as well as for skin resurfacing procedures. It is also indicated for treatment of dyschromia and cutaneous lesions, such as, but not limited to lentigos (age spots), solar lentigos (sun spots), actinic keratosis, and melasma, and for treatment of periorbital wrinkles, acne scars and surgical scars.

1927 nm: The Fraxel re:store 1927 nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue and the treatment of actinic keratosis.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

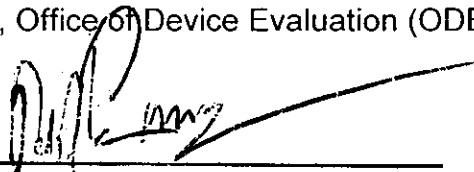
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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

Page 1 of 1

510(k) Number

K101490