K080911

JUL - 1 2008

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

REGULATORY AUTHORITY

Safe Medical Devices Act of 1990, 21 CFR 807.92

COMPANY NAME/CONTACT

Heather MacFalls
Reliant Technologies, Inc.
464 Ellis St.
Mountain View, CA 94043
650 605-2257
650 605-2057 fax
hmacfalls@fraxel.com

NAME OF DEVICE

Trade Name:	Fraxel re:pair™ (Fraxel III SR) Laser System and Accessories
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:pair (Fraxel III SR) Laser System and Accessories
510(k) #: K063038, K071051

Name: Lumenis UltraPulse Encore Carbon Dioxide Surgical Laser and Delivery Device Accessories
510(k) #: K022060, K030147

DEVICE DESCRIPTION

The Fraxel re:pair Laser System consists of a CO_2 laser source and three delivery handpieces for resurfacing, incision and debulking procedures. Each handpiece attaches to an articulating arm. Additional device accessories include interchangeable resurfacing treatment tips, incisional handpiece spatulas, and debulking handpiece spatulas.

K070915

INDICATION FOR USE STATEMENT

The Fraxel re:pair (Fraxel III SR) Laser System, including its resurfacing handpiece delivery system, is intended for use in:

-Dermatological procedures requiring ablation (removal), resurfacing and coagulation of soft tissue.
-Treatment of wrinkles, rhytides, furrows, fine lines;
-Pigmented lesions;
-Textural irregularities;
-Vascular dyschromia.

The Fraxel re:pair (Fraxel III SR) Laser System, including its incisional and debulking delivery systems, are intended for ablation (removal), for the reduction, treatment and/or removal of:

- Actinic and seborrheic keratoses;
-Chelitis;
-Cutaneous horns;
-Hemangiomas;
-Keloids;
-Nevi, including spider, epidermal and protruding;
-Rhinophyma;
-Syringomas;
-Warts;
-Laser incision and/or excision for the performance of upper and lower eyelid blepharoplasty and vermilionectomy of the lip.

SUBSTANTIAL EQUIVALENCE COMPARISON

Indications for Use

Substantial equivalence for the Fraxel re:pair Laser System and Accessories is supported by the predicate devices listed in this submission, which have identical or similar indications for use statements and equivalent performance specifications.

Clinical Performance Data

Non-Significant Risk and Investigational Device Exemption studies to support the clinical performance of the Fraxel re:pair Laser System and its resurfacing handpiece. The substantial equivalence of the incisional and debulking handpieces supported the determination of safety and effectiveness for the Fraxel re:pair Laser System and Accessories. Unique device features do not introduce new issues of safety and effectiveness.

K080915

Technological Characteristics

Key technological characteristics for the resurfacing, incisional and debulking delivery systems for the Fraxel re:pair Laser System, such as energy type and operating principle, are equivalent to the Fraxel re:pair Laser System as described in submissions K063038 and K071051 and to the Lumenis Ultrapulse Encore Laser System as described in K020660 and K030147.

CONCLUSION

Based on the design, materials, function, specifications and intended use, the Fraxel re:pair Laser System and Accessories is substantially equivalent to the devices currently marketed under the Federal Food, Drug and Cosmetic Act. Safety and effectiveness are reasonably assured, justifying 510(k) clearance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 1 2008

Reliant Technologies, Inc.
% Ms. Heather MacFalls
Clinical and Regulatory Affairs
464 Ellis Street
Mountain View, California 94043

Re: K080915
Trade/Device Name: Fraxel re:pair (Fraxel III SR) 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: II
Product Code: GEX
Dated: March 31, 2008
Received: April 02, 2008

Dear Ms. MacFalls:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K080915

Device Name: Fraxel re:pair (Fraxel III SR) Laser System and accessories
Indications For Use:

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-Dermatological procedures requiring ablation (removal), resurfacing and coagulation of soft tissue.
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-Textural irregularities;
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-Hemangiomas;
-Keloids;
-Nevi, including spider, epidermal and protruding;
-Rhinophyma;
-Syringomas;
-Warts;
-Laser incision and/or excision for the performance of upper and lower eyelid blepharoplasty and vermilionectomy of the lip.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

(Division Sign-Off)
Division of Dermatological and Dental Restorative, and Neurological Devices
510(k) Number K080918