K053047

APPENDIX A

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

K053047

510(k) SUMMARY

As required by Section 12 of the Medical Devices Act of 1990, Reliant technologies, Inc. is providing a summary of safety and effectiveness information available for Reliant Technologies, Inc. Laser System, as well as the substantial equivalence decision making process.

Submitter: Reliant Technologies, Inc.
Address: 464 Ellis St.
Mountain View, CA 94043

Contact Person: Heather Tanner
Clinical and Regulatory Affairs
Telephone: (650) 641-5861
Facsimile: (650) 641-3641

Date prepared: October 27, 2005

Device Trade Name: Fraxel SR Laser System

Common Name: Dermatology Laser

Classification Name: Laser Surgical Instrument
21 C.F.R § 878.4810

Legally Marketed Predicate Devices:
Fraxel SR Laser System K050841
Candela VBeam K033461
Candela CBeam K033331
Candela Smoothbeam K041242
CoolTouch CT3 K043046
Lumenis Ultrapulse Encore K022060

Description of the Fraxel SR Laser System

The Fraxel SR Laser System consists of a set of fiber lasers, controlled by an embedded processor, to be used in dermatology. The laser system uses scanning and focusing optics to deliver a pattern of thermal energy to the epidermis and upper dermis. Device accessories include tip attachments.

Indications for Use

The Reliant Laser System II is intended for use in:

Dermatological procedures requiring the coagulation of soft tissue;

Treatment of periorbital wrinkles;

Treatment of surgical scars and acne scars;

Photocoagulation of pigmented lesions, such as, but not limited to lentigos (age spots), solar lentigos (sun spots), melasma and dyschromia;

Skin resurfacing procedures.

Compliance to 21 CRF 1040

As a laser product, the Fraxel SR Laser System is required to conform and does conform to the requirements of 21 CFR 1040.

Substantial Equivalence Comparison

The technological characteristics and indications for use of the Fraxel SR Laser System are similar to those of the cited predicate laser devices. These devices are equivalent in terms of design, materials, principal of operation, and product specifications. Any differences between the Reliant Technologies Laser System II and the predicate devices do not raise new issues regarding safety or effectiveness.

Clinical Performance Data

Clinical performance data was used to demonstrate that the Fraxel SR Laser System functioned as clinically intended. The results from clinical investigation allowed for the determination that the Fraxel SR Laser System performs as clinically intended and that no new issues of safety and effectiveness are introduced.

Conclusion

Based on the design, materials, function, intended use, and clinical evaluation, the Fraxel SR Laser System is substantially equivalent to the devices currently marketed under the Federal Food, Drug and Cosmetic Act. In addition, the Fraxel SR Laser System raises no new safety or effectiveness issues. Therefore, safety and effectiveness are reasonably assured, justifying 510(k) clearance for commercial sale.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2006

Reliant Technologies, Inc.
c/o Ms. Heather Tanner
Clinical Research/Regulatory Affairs
Manager
464 Ellis Street
Mountain View, California 94043

Re: K053047
Trade/Device Name: Reliant Laser System II and accessories (Fraxel SR Laser System)
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: February 16, 2006
Received: February 17, 2006

Dear Ms. Tanner:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Acting 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): K053047

Device Name: Reliant Laser System II and accessories **(Fraxel SR Laser System)**

Indications For Use:

"The Reliant Laser System II and accessories (Fraxel SR Laser System) is intended for use in:

Dermatological procedures requiring the coagulation of soft tissue;

Treatment of periorbital wrinkles;

Treatment of surgical scars and acne scars;

Photocoagulation of pigmented lesions, such as, but not limited to lentigos (age spots), solar lentigos (sun spots), melasma and dyschromia;

Skin resurfacing procedures."

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K053047