510(k) Summary of Safety and Effectiveness for the SLIM Evolution Family of CO2 Lasers and Delivery Device Accessories

K063001

1. General Information

Submitter: Lasering S.r.l
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Modena, 4110 Italy

MAR 07 2007

Contact Person: Allen R. Howes
TTI Medical
2246 Camino Ramon
San Ramon, CA 94583
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Preparation Date: September 25, 2006

2. Device Name:

Trade/Proprietary Name: SLIM Evolution Family of CO2 Lasers and Delivery Device Accessories
Common/Usual Name: General Surgical Laser System
Classification Name: Laser Instrument, Surgical Powered
Product Code: GEX
Panel: 79

3. Predicate Devices:

The SLIM Evolution Family of CO2 Lasers are substantially equivalent the predicate devices Aesculap-Meditec Multipulse (K002032), Coherent Ultrapulse 2500C (K963339) and Lumenis Ltd.(formerly Sharplan Lasers Inc) Model 20C, 30C and 40C Surgical Lasers (K963229).

The SLIM Evolution Delivery Device Accessories are substantially equivalent to predicate delivery devices – Sharplan focused spot handpieces with reusable tip accessories (K933918) – Sharplan fiber/waveguide handpieces (K900076 and K950725) – Sharplan Scanner devices – K955621, K960521 and K963339) – Sharplan micromaniplutors – (K933918, K881953 and K951204).

4. Device Description:

The SLIM Evolution Family of CO2 Lasers emit a beam of coherent light at the wavelength 10.6 microns in either continuous wave or pulse mode. Each laser consists of a self-contained console, an articulated arm delivery system, a footswitch, safety goggles and warning label set. The main console contains a DC-excited sealed-off CO2 gas tube, micro-controller, articulated arm mount, internal closed circuit cooling system and power supply. The console has an on-off key switch and emergency stop push button. The articulated arm connects the console to focusing handpieces, waveguides, scanner and micromanipulator delivery accessories. Refer to the enclosed brochure and instruction manual for complete published information.

5. Intended Use:

The SLIM Evolution Family of CO2 Lasers and delivery device accessories are intended for use in surgical applications that require ablation, vaporization, excision, incision and coagulation of soft tissue in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.

6. Performance Data: None provided

7. Clinical Data: None provided

8. Conclusion:

The SLIM Evolution Family of CO2 Lasers and delivery device accessories are substantially equivalent to predicate CO2 laser systems in commercial distribution for use in Dermatology, Plastic Surgery, General Surgery, Dental, Podiatry, Otorhinolaryngology and Gynecology.

Indications for Use

510(k) Number _____

Device Name: SLIM Evolution Family of CO2 Lasers and Delivery Device Accessories.

Indications For Use: Continued from previous page

Dental procedure including but not limited to -
Periodontal procedures such as – gingivectomy, removal of hyperplasias,gingivoplasty (incision and excision)
Oral Surgery procedures such as – aphous ulcer excision, frenectomy, benign/malignant lesion ablation, operculectomy and homeostasis

Podiatry procedures including but not limited to -
Ablation, vaporization and excision of soft tissue lesions such as ingrown nail, fungal nail, porokeratoma, matrixectomy and verrucae vulgares.

Otorhinolaryngology (ENT) procedures including but not limited to -
Treatment of leukoplakia of larynx, nasal obstruction, rhinophyma, verrucrea vulgares, choanal atresia, rhinophyma, LAUP and papillomatosis polyps.

Gynecology
Treatment of condyloma acuminata, cervical intraepithelial neoplasia, leukoplakia and vulvar/vaginal intraepithelial neoplasia, cervical dysplasia.
Laparoscopic treatment endometrial lesions, ablation of endometriosis, fimbroplasty,
Tubal microsurgery, salpingostomy, histerectomy, uterine myomas and fibroids

Prescription Use X AND/OR Over-The-Counter Use _____
(part21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Lasering S.R.L.
% TTI Medical
Mr. Allen R. Howes
President
2246 Camino Ramon
San Ramon, California 94583

MAR 07 2007

Re: K063001
Trade/Device Name: SLIM Evolution Family of CO2 Lasers and Delivery Device 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: February 27, 2007
Received: February 28, 2007

Dear Mr. Howes:

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.

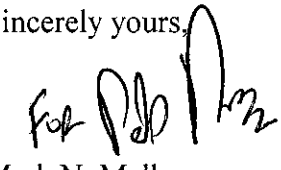
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 (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 K063001

Device Name: SLIM Evolution Family of CO2 Lasers and Delivery Device Accessories.

Indications For Use:

The SLIM Evolution Family of CO2 Lasers and delivery device accessories are intended for use in surgical applications that require ablation, vaporization, excision, incision and coagulation of soft tissue in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.

Dermatology, Plastic Surgery and General Surgery procedures including but not limited to -

Laser skin resurfacing
Treatment of furrows and wrinkles
Removal of skin tags, actinic keratosis, acne scars, keloids, tattos, telangiectasia, squamous and basel cell carcinoma, warts and uneven pigmentation.
Treatment of cysts, abscesses, hemorrhoids and other soft tissue applications.
Blepharoplasty
Site preparation for hair transplants

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

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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices 7-3

510(k) Number K063001