K 063396

510(k) Summary of Safety and Effectiveness for the Velure Family of Diode Lasers and Delivery Device Accessories

1. General Information

JAN 17 2007

Submitter: Lasering S.r.l
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TTI Medical
2246 Camino Ramon
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925-355-0750
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Preparation Date: November 6, 2006

2. Device Name:

Trade/Proprietary Name: Velure Family of Diode 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 Velure Family of Diode Lasers and deliver device accessories are substantially equivalent to the predicate devices Adept Ultralite 532 (K042496) and the Intermedic Diode Laser Family (K053540.

4. Device Description:

The Velure Family of Diode Lasers emit a beam of coherent light in either continuous wave or pulse mode at the following wavelengths.
523nm - Velure S5
808nm - Velure S8/15, Velure S8/30 and Velure S800
980nm - Velure S9/7D, Velure S9/15, Velure S9/15D and Velure S9/30

Each laser consists of a self-contained console, an SMA fiber delivery system with handpiece, a footswitch, safety goggles and warning label set. The main console contains a Diode laser, a 635nm pilot laser, micro-controller, air cooling system and power supply. The console has an on-off key switch and emergency stop push button. The SMA fiber delivery system connects the console to a variety of fiber optic handpieces and scanner (Velure S5 only). Refer to the enclosed brochures and instruction manuals for complete published information.

5. Intended Use:
The Velure Family of Diode Lasers are intended for use in dermatology, hair removal, oral, periodontal and surgical applications that require ablation, vaporization, excision, incision and coagulation of soft tissue.

Velure S5
532nm (Green) Diode Laser

Applications:

Vascular Lesions

Pigmented Lesions

Velure S8/15, Velure S8/30 and Velure S800
808nm Diode Laser

Applications:

Vascular Lesions

Unwanted Hair Removal

Velure S9/15 and Velure S9/30
980nm Diode Laser
Applications:
Surgical
- Cut and coagulate
- General Surgery
- GYN
- ENT
- Neuro
- Urology

Velure S9/7D and Velure S9/15D
980nm Diode Laser
Applications:
Oral and Periodontal Surgery

Bleaching (tooth whitening)

Specifications – Refer to pages 5 and 6 in the Instruction Manuals for published specifications

6. **Performance Data:** None provided

7. **Clinical Data:** None provided

8. **Conclusion:**
The Velure Family of Diode Lasers and delivery device accessories are substantially equivalent to predicate diode laser systems in commercial distribution for use in Dermatology, Aesthetic Surgery, Plastic Surgery, General Surgery, Dentistry, ENT, Neurosurgery and Gynecology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JAN 17 2007

Re: K063396
Trade/Device Name: Velure Family of Diode 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: Class II
Product Code: GEX
Dated: November 6, 2006
Received: November 9, 2006

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) 276-0210 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 K 063396

Device Name: Velure Family of Diode Lasers and Delivery Device Accessories.

Indications For Use:

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Velure S5
532nm (Green) Diode Laser

Applications:

Vascular Lesions

Pigmented Lesions

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

510(k) Number K063396

Indications for Use

510(k) Number K 063396

Device Name: Velure Family of Diode Lasers and Delivery Device Accessories.

Indications For Use: Continued from previous page

Velure S8/15, Velure S8/30 and Velure S800
808nm Diode Laser

Applications:
Vascular Lesions

Unwanted Hair Removal

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

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

Indications for Use

510(k) Number K 063396

Device Name: Velure Family of Diode Lasers and Delivery Device Accessories.

Indications For Use: Continued from previous page

Velure S9/15, Velure S9/30
980nm Diode Laser

Applications:
Surgical
Cut and coagulate
General Surgery
GYN
ENT
Neuro
Urgology

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

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Indications for Use

510(k) Number K 063396

Device Name: Velure Family of Diode Lasers and Delivery Device Accessories.

Indications For Use: Continued from previous page

Velure S9/7D and Velure S9/15D
980nm Diode Laser

Applications:
Oral and Periodontal Surgery

Bleaching (tooth whitening)

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

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