



Surgical
Laser
Technologies

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JAN 27 2003

7.

510(k) SUMMARY
SLT Venous Fiber Delivery Systems

K023624

This 510(k) summary of safety and effectiveness information for the SLT Venous Fiber Delivery Systems is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____

Applicant: Surgical Laser Technologies, Inc.

Address: Surgical Laser Technologies, Inc.
147 Keystone Drive
Montgomeryville, PA, 18936

Contact Person: Davis Woodward
Vice President, CFO

Telephone: (215) 619 3600
(215) 619 3209 (fax)

Preparation Date: October 9, 2002

Proprietary Device Name: "SLT Venous Fiber Delivery Systems", comprised of the following models:

Model Name	Model Number
Venous Flat Fiber, SLT	0041-6772
Venous Flat Fiber, SMA-905	0041-6781
Venous Conical Fiber, SLT	0041-6752
Venous Conical Fiber, SMA-905	0041-6761
Venous Diffuser Fiber, SLT	0041-6912
Venous Diffuser Fiber, SMA-905	0041-6921

Common Name: Surgical Laser Fiber Delivery System

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (see 21 CFR 878.4810).

Product Code: GEX

Panel: 79, General and Plastic Surgery

**Legally Marketed
Predicate Devices:**

Diomed 810nm Surgical Lasers and EVLT Procedure Kit (K012398)
VNUS® Closure™ System (K003092)
VNUS® Closure™ System (K982816)
VNUS® Closure™ System (K974521)
Ceralas D10-60 810nm Diode Laser System and ELVS Procedure Kit
(K020835)
Ceralas D Diode 980nm Laser System (K013691)

**Description of the
Device:**

SLT Venous FDS products include the Venous Diffusing Fiber, the Venous Conical Fiber, and the Venous Flat Fiber.

SLT Venous Diffuser Fibers are flexible fibers with an active diffusing portion that diffuses the laser energy in a uniform pattern about its active diffusing length, resulting in a cylindrical or elongated spheroidal zone of coagulation.

SLT Venous Conical Fibers splay the laser energy radially at their distally conical portion, providing a much smaller and more focused coagulation zone than the Venous Diffuser Fiber.

SLT Venous Flat Fibers direct the laser energy forward from their distally flat end, providing the highest energy density of the three SLT Venous Fibers.

SLT Venous Fibers are available with SLT proprietary connectors (to fit SLT Contact Laser™ Systems) and SMA-905 connectors (to fit lasers with standard SMA-905 launch interfaces).

SLT Venous Diffuser Fibers are compatible for use only with lasers having wavelengths between 980nm and 1064nm.

SLT Venous Conical and Flat Fibers are compatible for use with lasers having wavelengths between 810nm and 1064nm.

SLT Venous Fibers are flexible and therefore, when used for endovascular applications, a catheter, cannula, or similar device should be used to insert the fiber into the vein.

SLT Venous Fiber products are sold sterile, and are intended for single use only.

Indications for Use:

The SLT Venous Fiber is intended for use in endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.

**Substantial
Equivalence:**

The intended use, method of tissue interaction, specifications, clinical technique and animal study results of the SLT Venous Conical and Flat Fiber Delivery Systems are the same or very similar to those of the legally marketed fiber delivery system in the Diomed 810 Surgical Lasers and EVLT™ Procedure Kit (K012398), to the legally marketed Ceralas D10-60 810nm Diode Laser System and ELVS Procedure Kit (K020835), and to the legally marketed Ceralas D Diode 980nm Laser System (K013691).

The intended use, method of tissue interaction (thermal), clinical technique and animal study results of the SLT Venous Diffuser Fiber Delivery System is the same or very similar to those of the legally marketed VNUS® Closure™ System (K003092, K982816, K974521).

The intended use, method of tissue interaction (thermal), clinical technique and animal study results of the SLT Venous Flat Fiber Delivery System is the same or very similar to those of the legally marketed Ceralas D Diode 980nm Laser System (K013691).

**Safety and
Effectiveness:**

Animal studies have demonstrated the substantially equivalent safe and effective performance of the SLT Venous Conical and Flat Fiber Delivery Systems with the legally marketed fiber delivery system in the Diomed 810 Surgical Lasers and EVLT™ Procedure Kit (K012398) to the legally marketed Ceralas D10-60 810nm Diode Laser System and ELVS Procedure Kit (K020835), and to the legally marketed Ceralas D Diode 980nm Laser System (K013691).

Animal studies have demonstrated the substantially equivalent safe and effective performance of the SLT Venous Flat Fiber Delivery System with the legally marketed VNUS® Closure™ System (K003092, K982816, K974521).

The intended use, method of tissue interaction (thermal), clinical technique and animal study results of the SLT Venous Flat Fiber Delivery System is the same or very similar to those of the legally marketed legally marketed Ceralas D Diode 980nm Laser System (K013691).

The materials used in the SLT Venous Fiber Delivery Systems are biocompatible.

Toxological testing and evaluation per both USP Class VI and ISO 10993-1, including hemocompatibility testing per ISO 10993-4, were successfully performed.

Conclusion:

Based on the foregoing, Surgical Laser Technologies, Inc., believes that the SLT Venous Fiber Delivery Systems are substantially equivalent to and as safe and effective as the legally marketed fiber delivery system in the Diomed 810 Surgical Lasers and EVLT™ Procedure Kit (K012398), the legally marketed VNUS® Closure™ System (K003092, K982816, K974521), the legally marketed Ceralas D10-60 810nm Diode Laser System and ELVS Procedure Kit (K020835), and the Ceralas D Diode 980nm Laser System (K013691).



JAN 27 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Surgical Laser Technologies, Inc.
Davis Woodward
Vice President, CFO
147 Keystone Drive
Montgomeryville, Pennsylvania 18936

Re: K023624
Trade/Device Name: SLT Venous Fiber Delivery Systems
Regulation Number: 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: October 25, 2002
Received: October 29, 2002

Dear Mr. Woodward:

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 (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. STATEMENT OF INDICATIONS FOR USE

<p>Applicant: Surgical Laser Technologies, Inc. 147 Keystone Drive Montgomeryville, PA, 18936 Establishment registration number: 2523356</p> <p>510(k) Number (if known): <u>K023624</u></p> <p>Device Name: SLT Venous Fiber Delivery Systems</p> <p>Indications for Use: The SLT Venous Fiber is intended for use in endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux. (PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)</p>
<p>Concurrence of CDRH, Office of Device Evaluation (ODE)</p>

Prescription Use OR Over-The-Counter Use
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023624