

Attachment I
510(K) Summary
LS Family of CO2 Lasers

OC1 8 - 2004

K040563

This 510(K) Summary of safety and effectiveness for the LS-15 and LS-25 CO2 Laser System is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant: Sandstone Medical Technologies, LLC

Address: Sandstone Medical Technologies LLC
516 Scott Street
Homewood, AL 35209 USA

Contact Person: Mr. Mark Rohrer

Telephone: 1-205-290-8251- Phone

Preparation Date: September 22, 2001

Device Trade Name: LS Family of CO2 Lasers including :
LS-15 CO2 Laser System
LS-25 CO2 Laser System

Common Name: CO2 Surgical Laser

Classification Name: Instrument, Surgical, Powered, laser
79-GEX, 21 CFR 878-48

Legally Marketed Predicate Device: UltraPulse CO2 Surgical Laser K030147
Luxar LX-20SP Surgical Laser K953074

Description of the LS Family of CO2 Lasers: The **LS Family of CO2 Lasers** are microprocessor-controlled CO2 laser systems using a sealed CO2 laser tube providing either 15 watts maximum power (LS-15) or 25 watts maximum power (LS-25). The system incorporates a CO2 laser tube within the main cabinet, an articulated arm beam delivery system and attachable laser accessories. The unit is activated for laser emission by a footswitch.

Intended use of the LS Family of CO2 Lasers: The LS Family of CO2 Lasers are intended to be used for Coagulation, vaporization, ablation or cutting of soft tissue in dermatology and plastic surgery, general surgery, podiatry and otorhinolaryngology.

Performance Data: None

Results of Clinical Study: None

Conclusion: The LS Family of CO2 Lasere are substantially equivalent to other existing CO2 Laser System in commercial distribution for use in Dermatology and Plastic Surgery.



OCT 8 - 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sandstone Medical Technologies, LLC
c/o Ms. Connie White Hoy
908 Stetson Street
Woodland, California 95776

Re: K040563

Trade/Device Name: Sandstone Medical Technologies LLC Family of LS CO₂ Lasers

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: July 5, 2004

Received: July 12, 2004

Dear Ms. Hoy:

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.

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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,

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

Indications for Use

510(k) Number (if known): K040563 K Pending

Device Name: Sandstone Medical Technologies LLC Family of LS CO2 Lasers

Indications For Use:

Coagulation, vaporization, ablation or cutting of soft tissue in dermatology and plastic surgery, general surgery, podiatry and otorhinolaryngology.

Prescription Use xx
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)

Miriam C. Paorost
(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

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