NOV - 5 2008

K082101

Attachment III
510(K) Summary
LS Family of CO2 Lasers with
Fractionated Handpiece

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

Applicant:	Sandstone Medical Technologies, LLC
Address:	Sandstone Medical Technologies, LLC 105 Citation Court Homewood, Alabama 35209
Contact Person:	Mark Rohrer
Telephone:	1-205-290-8251- Phone
Preparation Date:	July 20, 2008
Device Trade Name:	LS Family of CO2 Lasers
Common Name:	CO2 Laser
Classification Name:	Instrument, Surgical, Powered, laser 79-GEX, 21 CFR 878-48
Equivalent Device:	LS Family of CO2 Lasers cleared under K040563
Description of the LS Family System:	The LS Family of CO2 lasers are microprocessor-controlled laser systems that incorporate a handpiece to deliver energy to the tissue in a scanned, fractionated pattern.
Intended Use:	The scanning handpiece is intended to be used as an accessory to the LS Family of CO2 Lasers to deliver the laser light to the targeted area for skin resurfacing in a fractionated manner.
Performance Data:	None
Results of Clinical Study:	Histology was collected from a small sample of patients to determine the depth of penetration.
Conclusion:	The LS Family of CO2 Lasers with the additional scanning handpiece is substantially equivalent to the previously cleared LS Family of CO2 Lasers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sandstone Medical Technologies, LLC
% Mr. Mark Rohrer
Managing Member
105 Citation Court
Homewood, Alabama 35209

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Re: K082101
Trade/Device Name: Sandstone Medical Technologies Family of LS CO2 Lasers with Scanning Handpiece
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: September 24, 2008
Received: September 29, 2008

Dear Mr. Rohrer:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (if known): K Pending K082101

Device Name: Sandstone Medical Technologies Family of LS CO2 Lasers with Scanning Handpiece

Skin Resurfacing

Prescription Use xx AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 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)

for MKM

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

510(k) Number K082101