K081219

Attachment 5
510(K) Summary
Apollo Mini IPL System

JUN 30 2008

This 510(K) Summary of safety and effectiveness for the Apollo Mini IPL 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 102 Oxmoor Road Suite 13 Homewood, AL 35209
Contact Person:	Mr. Mark Rohrer
Telephone:	1-205-290-8251– Phone
Preparation Date:	April 15, 2008
Device Trade Name:	Apollo Mini IPL System
Common Name:	Intense Pulsed Light
Classification Name:	Instrument, Surgical, Powered, laser 79-GEX, 21 CFR 878-48
Legally Marketed Predicate Device(s):	NaturaLight System 510(K) 041829. Radiancy Acne System with ClearTouch Light Unit K 032205 OmniLight FPL System K 032191
Description of the Apollo Mini IPL System:	The Apollo Mini IPL System delivers pulsed light at wavelengths starting at 450-1200nm nanometers. The device consists of the cabinet, which houses the power supply, the cooling system and the microcontroller, the umbilical to the handpiece, and the handpiece, which houses the waveguide.
Intended use of the Apollo Mini IPL System:	The Apollo Mini IPL systems is intended to be used by providing phototherapeutic light for Hair Removal, Permanent hair reduction, Treatment of vascular lesions, Treatment of benign pigmented lesions, Mild to Moderate inflammatory acne. The Apollo Mini-IPL is indicated for use on skin types I-IV.
Performance Data:	None
Results of Clinical Study:	None
Conclusion:	The Apollo Mini IPL System is substantially equivalent to other existing IPL Systems in commercial distribution for use in Dermatology and Plastic Surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 2008

Sandstone Medical Technologies, LLC
% Mr. Mark Rohrer
102 Oxmoor Road, Suite 13
Homewood, Alabama 35209

Re: K081219
Trade/Device Name: Sandstone Medical Technologies LLC Apollo Mini IPL System
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: June 11, 2008
Received: June 18, 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

Device Name: Sandstone Medical Technologies LLC Apollo Mini IPL System

The Apollo Mini-IPL System is indicated for use skin types I-IV according to the Fitzpatrick Scale for the following indications:

Hair Removal
(650nm filter)

Permanent hair reduction
(650nm filter)

Treatment of vascular lesions
(510nm filter)

Treatment of benign pigmented lesions
(510nm filter)

Mild to Moderate inflammatory acne
(450nm filter)

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

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

510(k) Number K081215