

K110502

APR 27 2011

This 510(K) Summary of safety and effectiveness for the Triplex Er:YAG / Nd:YAG 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: 105 Citation Court
Birmingham, AL 35209

Contact Person: Mark Rohrer

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Preparation Date: February 15, 2011

Device Trade Name: Triplex Er:YAG / Nd:YAG Laser System

Common Name: ER:YAG Laser and Nd:YAG Laser

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

Legally Marketed Predicate Device: MLT Erbium:YAG Laser System (K)032599
Ultralight II Nd:YAG Laser System (K)082407

Description of the Triplex Er:YAG / Nd:YAG Laser System: The Apex system and controls are contained in a single console. Electrical power is supplied to the console by the facility's power source. There are 2 handpieces with the system. One is an Er:YAG laser which contains the laser cavity in the head of the handpiece. The second is an Intense Pulsed Light. These handpieces can be removed by the user and interchanged. The Er:YAG Laser energy is a wavelength of 2940nm.

This handpiece can be removed and replaced with a q-switch Nd:YAG handpiece emitting wavelengths of 1064nm and 532nm laser energy can be added.

The user activates the laser emission by means of a footswitch.

Intended use of the Triplex Er:YAG / Nd:YAG Laser System: The Er:YAG handpiece is designed specifically for superficial skin ablation resulting in skin dermabrasion, and the treatment of wrinkles. In addition this system is intended for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery).

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The Nd:YAG handpiece is indicated for:

- At the 1064nm wavelength - dark ink tattoo removal, removal of pigmented lesions and the removal or lightening of hair.
- At the 532nm wavelength - removal of red ink tattoos, treatment of vascular lesions including facial and leg veins, telangiectasias, angiomas, hemangiomas, port wine stains and most pigmented lesions (e.g. lentigies, ephildes)

Performance Data: None

Results of Clinical Study: None

Summary of Technological Characteristics:

	Sandstone Medical Technologies LLC Triplex Er:YAG / Nd:YAG System	Sandstone Medical Technologies LLC Nd:YAG (Predicate Device)
Energy	Up to 1000mJ	Up to 1000mJ
Maximum Fluence	12J/cm ²	12J/cm ²
Wavelength	1064nm and 532nm	1064nm and 532nm
Spot Size	up to 5mm	up to 5mm
Pulse Width	10ns	10ns
Repetition Rate	1-5Hz	1-5Hz
Aiming Beam	HeNe	HeNe

	Sandstone Medical Technologies LLC Triplex Er:YAG / Nd:YAG Laser System	Sandstone Medical Technologies LLC Er:YAG Laser (Predicate)
Wavelength	2940nm	2940nm
Max Power	2.4 W	2.4 W
Max Fluence	8 J/cm ²	8 J/cm ²
Pulse Width	300 μs	300 μs
Repetition Rate	Up to 10 pulse per second	Up to 10 pulse per second
Spot Size	1.5mm, 3mm, 6mm, 9mm	1.5mm, 3mm, 6mm, 9mm

Attachment 5
510(K) Summary
Triplex Er:YAG / Nd:YAG Laser System

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Conclusion:	The Triplex Er:YAG / Nd:YAG Laser System is comparable to the predicate device in terms of indications for use, technical specifications, operating performance features, general design.
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Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room --WO66-G609
Silver Spring, MD 20993-0002

APR 27 2011

Sandstone Medical Technologies, LLC
% Mr. Mark Rohrer
105 Citation Court
Birmingham, Alabama 35209

Re: K110502

Trade/Device Name: Triplex Er:YAG / Nd:YAG Laser System
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: February 14, 2011
Received: February 22, 2011

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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

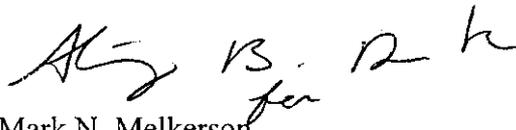
Page 2 – Mr. Mark Rohrer

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson" with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

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

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Device Name: Triplex Er:YAG / Nd:YAG Laser System

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The Nd:YAG handpiece is indicated for:

- At the 1064nm wavelength - dark ink tattoo removal, removal of pigmented lesions and the removal or lightening of hair.
- At the 532nm wavelength - removal of red ink tattoos, treatment of vascular lesions including facial and leg veins, telangiectasias, angiomas, hemangiomas, port wine stains and most pigmented lesions (e.g: lentigies, ephildes)

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)

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Neil R. Dyden for MCM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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