K083272 8 1 of 2

DEC 16 2008

510(k) Summary

Global USA Distribution, LLC
SkinClear Q-Switched Nd:YAG Laser

Submitter:	Global USA Distribution, LLC
Address:	10723 Aquila Av. S. Minneapolis, MN 55438
Contact Person:	Matt Makousky
Telephone:	952-703-5373
Facsimile:	952-888-8887
Date Prepared:	July 1, 2008
Device Trade Name:	SkinClear Q-Switched Nd:YAG Laser
Classification Name:	Instrument, Powered, Laser

Legally Marketed Predicate Devices: Sandstone Medical Technologies, LLC
UltraLight II Nd:YAG Laser System (K041011)

Description of the SkinClear Q-Switched Nd:YAG Laser:

The SkinClear Q-Switched Nd:YAG Laser is composed of a console which houses a power supply, electronic circuit board, cooling system, a liquid crystal display screen (LCD), a handpiece which contains the light source which is connected to the console by a power cord, and an on/off footswitch.

Intended Use of the : SkinClear Q-Switched Nd:YAG Laser:

The SkinClear Q-Switched Nd:YAG Laser is indicated at the 1064 nm wavelength for dark ink tattoo removal, the removal of pigmented lesions, and the removal or lightening of hair. Indicated for use on all skin types (Fitzpatrick I-IV).

The SkinClear Q-Switched Nd:YAG Laser is indicated at the 532 nm wavelength for red ink tattoo removal, treatment of vascular lesions including facial and leg veins, telangiectasias, angiomas, hemangiomas, port wine stains, and most pigmented lesions (e.g. lentigines, ephildes). Indicated for use on all skin types (Fitzpatrick I-IV).

Summary of technological characteristics:

The SkinClear Q-Switched Nd:YAG Laser and the Sandstone Medical Technologies, LLC UltraLight II Nd:YAG Laser System share the same wavelengths, energy output, pulse duration, and pulse repetition rate.

Nonclinical Performance Data:	None
Clinical Performance Data:	None
Additional Information:	None requested at this time
Conclusion:	The SkinClear Q-Switched Nd:YAG Laser is substantially equivalent to other existing legally marketed laser systems currently in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Global USA Distribution, LLC
% Underwriters Laboratory, Inc.
Mr. Ned Devine
333 Pfingsten Road
Northbrook, Illinois 60062

DEC 1 6 2008

Re: K083272
Trade/Device Name: SkinClear™ Q-Switched 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: II
Product Code: GEX
Dated: December 3, 2008
Received: December 4, 2008

Dear Mr. Devine:

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

K083272 p. 1 of 1

Indications for Use

510(k) Number (if known): _____

Device Name: SkinClear™ Q-Switched Nd:YAG Laser System

Indications for Use:

The SkinClear Q-Switched Nd:YAG Laser is indicated at the 1064 nm wavelength for dark ink tattoo removal, the removal of pigmented lesions, and the removal or lightening of hair. Indicated for use on all skin types (Fitzpatrick I-IV)

The SkinClear Q-Switched Nd:YAG Laser is indicated at the 532 nm wavelength for red ink tattoo removal, treatment of vascular lesions including facial and leg veins, telangiectasias, angiomas, hemangiomas, port wine stains, and most pigmented lesions (e.g. lentigines, ephildes). Indicated for use on all skin types (Fitzpatrick I-IV)

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

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

N. P. Dyke for mm

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

510(k) Number K083272