JUL 2 3 2002

K021304

SECTION 10

510(k) SUMMARY

This 510(k) summary of safety and effectiveness for the ProLite™ Pulsed Light System is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.


Applicant: Big Sky Laser Technologies, Inc.

Address: 601 Haggerty Lane, Suite C
Bozeman, MT 59715

Manufacturer: Big Sky Laser Technologies, Inc

Contact Person: Mr. Patrick Maine
President/CEO

Telephone: 406-586-0131
406-586-2924 (Fax)


Preparation Date: April 2002
(of the Summary)

Device Name: ProLite™ Pulsed Light System

Common Name: Pulsed Flash Lamp

Classification: Instrument, Surgical powered laser (claimed predicate)
(Name) Class II medical device; (21 CFR 878.4810)

Product Code: GEX
Panel: 79

Predicate devices: The ProLite™ Pulsed Light System is substantially equivalent to itself.

Device description: The ProLite™ Pulsed Light System uses a Xenon Flash Lamp which is filtered to specified wavelengths for its intended uses. The System consists of a cabinet with power supply, a distilled water cooling system, the microcontroller, an umbilical which attaches to a handpiece which houses the selected filter.

Indications: The ProLite™ Pulsed Light System, equipped with the HR handpiece and 600 nanometer filter, is intended for the removal of unwanted hair in all Fitzpatrick skin types.

The ProLite™ Pulsed Light System, equipped with the SR handpiece and 550 or 580 nanometer filter, is intended for the treatment of benign pigmented lesions and the removal of tattoos, the treatment of vascular lesions, and the treatment of shallow facial veins, telangiectasia, facial hemangiomas, and rosacea vascular lesions

The 550 nanometer filter may be more efficient for Types I and II skin.
The 580 nanometer filter may be more efficient for Types III and IV skin.

The Center for Medical Devices and Radiological Health has concluded that the ProLite™ Pulsed Light System be labeled as a restricted device as follows:

"CAUTION: Federal (US) law restricts the use of this device to licensed professionals."

Performance Data: None required. The claim of substantial equivalence is based on the fact that the ProLite™ Pulsed Light System described in this premarket notification is the same as described in several previous premarket notifications. No changes in specifications, performance characteristics, or indications for use are proposed.

CONCLUSION: Based on the information in the notification Big Sky Laser Technologies, Inc., believes that ProLite™ Pulsed Light System is substantially equivalent to itself, i.e., the claimed predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 3 2002

Mr. Patrick Maine
President and CEO
Big Sky Laser Technologies, Inc.
601 Haggerty Lane, Suite C
P.O. Box 8100
Bozeman, MT 59715

Re: K021304
Trade/Device Name: ProLite™ Pulsed Light System
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: April 19, 2002
Received: April 24, 2002

Dear Mr. Maine:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for Mark N Milkerson

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

SECTION 7

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K021304

Device Name: ProLite™ Pulsed Light System

Indications for Use Statement:

The ProLite™ Pulsed Light System, equipped with the HR handpiece and 600 nanometer filter, is intended for the removal of unwanted hair in all Fitzpatrick skin types.

The ProLite™ Pulsed Light System, equipped with the SR handpiece and 550 or 580 nanometer filters, is intended for the treatment of benign pigmented lesions and the removal of tattoos, the treatment of vascular lesions, and the treatment of shallow facial veins, telangiectasia, facial hemangiomas, and rosacea vascular lesions

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The 580 nanometer filter may be more efficient for Types III and IV skin.

The Center for Medical Devices and Radiological Health has concluded that the ProLite™ Pulsed Light System be labeled as a restricted device as follows:

"CAUTION: Federal (US) law restricts the use of this device to licensed professionals."

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The Counter Use ___
(Per 21 CFR 801.109)

for Mark N. Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021304

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