K093963

Section 6 510(k) Summary of Safety and Effectiveness

1. 510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	Silver Bay LLC
TRADE NAME:	Quasar Blue Light Therapy system
COMMON NAME:	Light Therapy system
CLASSIFICATION NAME:	Over-the-counter powered light based laser for acne
DEVICE CLASSIFICATION:	Class II, under 21 CFR, 878.4810,
PRODUCT CODE	Product Code OLP
PREDICATE DEVICES:	The "Quasar" Blue Light System for home use is identical to the company's previously cleared Quasar Blue Light Therapy System (K072767). Only the Operators Manual and the Patient Treatment Protocol have been modified to reflect the home use of the product. These documents have been amended to allow for an Over the Counter Indication for Use

AUG 27 2010

Substantially Equivalent To:
The Quasar Blue Light Therapy System is substantially equivalent in intended use, principal of operation and technological characteristics to the legally marketed Quasar Blue Light Therapy System (K072767).

Description of the Device Subject to Premarket Notification:

Indication for Use:
The "Quasar Blue" Blue Light Therapy System is intended to provide photo therapeutic light to the body. The "Quasar Blue" Blue Light Therapy System is generally indicated to treat dermatological conditions. The "Quasar Blue" Blue Light Therapy System is specifically indicated to emit visible blue/violet light to treat mild to moderate inflammatory acne vulgaris.

Technical Characteristics:
The Quasar Blue Light Therapy System has similar physical and technical characteristics to the predicate devices.

Performance Data:
All necessary testing has been performed for the Quasar Blue Light Therapy System to assure substantial equivalence to the predicate devices.

Basis for Determination of Substantial Equivalence:

Upon reviewing the safety and effectiveness information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the Quasar Blue Light Therapy System is determined by Silver Bay to be substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Silver Bay LLC
% Mr. Peter Nesbitt
1431 Tallevast Road
Sarasota, Florida 34243

AUG 27 2010

Re: K093963
Trade/Device Name: Quasar Blue Light Therapy 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: OLP
Dated: August 18, 2010
Received: August 18, 2010

Dear Mr. Nesbitt:

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

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" (21 CFR 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,

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 Statement

INDICATIONS FOR USE STATEMENT

AUG 2 7 2010

510(k) Number (if known): _____

Device Name: **"Quasar Blue" Light Therapy System**

Indications for Use:

The "Quasar Blue" Blue Light Therapy System is intended to provide photo therapeutic light to the body. The "Quasar Blue" Blue Light Therapy System is generally indicated to treat dermatological conditions. The "Quasar Blue" Blue Light Therapy System is specifically indicated to emit visible blue/violet light to treat mild to moderate inflammatory acne vulgaris.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

OR

Prescription Use ____
(Per 21 CFR 801.109)

Over-The-Counter Use__X___
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093963

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