JAN 1 8 2012

510(k) Summary

K 111286 1/3

Submission Date: March 15th, 2011

1. **Submitter Information:** AEGIS Regulatory, Inc. - Robert T. Wagner
1131 Anthem View Lane
Knoxville, TN 37922
Tel.: 865-982-5552
Email: bob@fdalistingconsultants.com

For Manufacturer: Silver Bay, LLC d/b/a Quasar Bio-Tech, Inc.
Attn: Peter Nesbitt
1431 Tallevast Rd.
Sarasota, FL 34231
Tel.: 941-306-5812
Email: peter@quasarpro.com

2. **General Information:**

2.1 Classification Name: LED Phototherapy/Laser Instrument, Surgical, Powered and Infrared lamp

2.2 Common/Usual Name: Quasar Calypso, C50

2.3 Proprietary/Trade Names: Quasar Calypso

2.4 Classification: Class II

2.5 Classification Number: 878.4810 and 890.5500

2.6 Product Codes: OLP

3. **Device Description:**

The Silver Bay Quasar Calypso C50 is a visible light and/or heat source with high spectral purity. The device is made of ABS plastic with clear polycarbonate lenses covering the LED light sources. The device is two-sided with one side emitting narrow band blue light at 405 to 420 nm. The opposite side of the device emits red light at 628 nm +- 10 nm. The device is operated by a momentary switch, which allows the operator to select either the blue or red operation. The device does not allow the operator to select the red and blue light simultaneously.

The Quasar Calypso C50 uses a 12 volt wall mount power supply.

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4. Indications / Intended Use:

The Quasar Calypso C50 is intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne vulgaris.

5. Predicate Device(s):

This device is substantially equivalent to the following predicate devices, which are currently in safe and effective commerce:

1. K093963 – Quasar Blue Light Therapy System (Silver Bay, LLC)
2. K060792 – Illumimed (PhotoActif)
3. K083183 – Aklarus (Hill Labs)
4. K081307 – Omnilux Clear-U (Photo Therapeutics, LTD)

6. Technological Characteristics:

The Quasar Calypso C50 has the same technological characteristics, design, material, chemical composition, and energy source as the cited predicate devices.

7. Performance Standards:

The device has been tested under and are in compliance with performance standards that have been established for such devices under Section 878 of the Federal Food, Drug, and Cosmetics Act. All electrical and radiological products made by the applicant have been OSHA/NRTL listed, and have received constituent marks and are in compliance with IEC/ EN 60601.

8. Biocompatibility:

The patient contact material on the Quasar Calypso C50 is polycarbonate plastic and is the same material used in the cited predicate devices. The biocompatibility of this material is well known and accepted.

9. Sterilization / Use:

The Quasar Calypso C50 is a non-sterile device, and therefore this section is not applicable Cleaning Instructions are in the User's Manual.

10. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety :

The device is in conformity with IEC/EN 60601-1-2000 and IEC/ EN 60601-1-2 Standards.

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11. Clinical Studies:

No Clinical Data is submitted with this application

12. Conclusion:

After an analysis of the safety, indications, intended uses, performance, features, design materials, power output, technological properties, treatment areas, treatment regimes and methods of operation, the manufacturer believes that no significant differences exist between the device and the predicates, therefore substantial equivalency is requested.

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 d/b/a Quasar Bio-Tech, Incorporated
% AEGIS Regulatory, Incorporated
Mr. Robert T. Wagner
1131 Anthem View Lane
Knoxville, Tennessee 37922

JAN 18 2012

Re: K111286
Trade/Device Name: Quasar Calypso C50
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: OLP
Dated: December 22, 2011
Received: December 27, 2011

Dear Mr. Wagner:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

for 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 STATEMENT

510(k) Number: K111286.

Device Name: Quasar Calypso C50

Indications for Use:

The Quasar Calypso C50 is intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate 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)

Mark R Ogden for mkm

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

510(k) Number K111286