510(K) Summary K091467.

This summary of 510(k) summary information is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the Baby Quasar Over the Counter Wrinkle Reduction Infrared Lamp.

This summary is submitted by:

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Contact: Peter Nesbitt
President, peter@quasarpro.com
Date prepared: 27 July 2010

SEP 17 2010

1. Device Identification:

Trade/Proprietary Name:	Baby Quasar
Common/Usual Name:	Light Therapy Device
Classification Names:	Wrinkle Reduction Device, 21 CFR § 878.4810

2 Predicate Devices:

The Baby Quasar Lamp is substantially equivalent to other devices on the market, such as the over the counter New-U (K072459) Photo Therapeutics Inc.

3. Indications for Use:

The Baby Quasar is a hand held device intended to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

4. Description of the Device:

The Baby Quasar consists of a collection of red and near infrared diodes [LEDs], packaged in a compact handheld device. The device has a head containing the led array, momentary switch, and indicator light.

5 Summary of the technological characteristics of the device
Compared to predicate devices:

The Baby Quasar and the above referenced predicate New-U device are Wrinkle Reduction Devices as defined in 21 CFR § 878.4810. These devices utilize red and infrared diodes [LEDs], to provide narrow bands of light energy to reduce wrinkles. The performance achieved by these devices are the same, using nearly identical power densities and wavelengths. The devices are handheld, and intended to be placed directly on the skin or held just over the skin to provide the heating. The predicate device is OTC (Over the counter) whereas ours is a prescription device.

6. Testing:

Testing of the Baby Quasar included functional performance testing (power levels), electrical safety testing, and Electromagnetic Compatibility Testing (EMC). The AC power supply is UL listed.

7. Rx or OTC:

The Baby Quasar is an Rx only device. The labeling, instructions, and User Operations (21 CFR § 801.60 and 61), are designed for physician understanding and use. The predicate device is OTC.

8. Conclusions:

Based upon the testing and comparison to the predicate devices, the Baby Quasar has the same intended uses, with similar technological characteristics as the predicate devices. The system performs as intended and does not raise any new safety or effectiveness issues.

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
% Kamm & Associates
Mr. Daniel Kamm, P.E.
333 Milford Road
Deerfield, Illinois 60015

SEP 17 2010

Re: K091467
Trade/Device Name: Baby Quasar
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general surgery and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ONE
Dated: September 09, 2010
Received: September 15, 2010

Dear Mr. Kamm:

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.

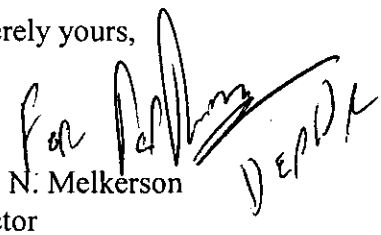
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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" (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,



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

Enclosure

K091467

Indications for Use

510(k) Number (if known): K091467.

SEP 17 2010

Device Name: Baby Quasar

Indications For Use:
This is a hand held device intended to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

Prescription Use X
(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)

Neil R. Ogden for mxn

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

510(k) Number K091467