K100628 Pg 1 of 2

NOV 2 4 2010

## 510(k) Summary

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

| | |
|---|---|
| **Submitter's Name:** | The Daavlin Distributing Company |
| **Registration Number:** | 1526255 |
| **Address:** | 205 West Bement Street<br>Bryan, Ohio 43506 |
| **Telephone:** | 419.636.6304 |
| **Contact:** | Michele Thiel |
| **Date Prepared:** | March 2, 2010 |
| **Device Trade Name:** | PlasmaLuxLS |
| **Device Common Name:** | Light Therapy Device |
| **Device Classification:** | Class II |
| **Product Code:** | ONE |
| **Regulation Number:** | CFR 878.4810, 890.5500 |
| **Regulation Name:** | Laser surgical instrument for use in General and Plastic surgery and in Dermatology. |

**Predicate Devices:**

| | |
|---|---|
| DUSA Pharmaceuticals, Inc. | BLU-U Blue Light Photodynamic Therapy Illuminator Model 4170 **K031805** |

K100628 pg 2 of 2

Lynton Lasers Limited LumaCare LC-122-M Non-coherent Light Source **K062871**

LIGHTWAVE Technologies LLC Lightwave Professional Deluxe **k083586**

**Device Description:**

The PlasmaLuxLS is a compact light source that delivers a uniform distribution of light, with spectral output at peak wavelengths of 417 nm (Blue Light) a It is intended for use by or under the direction of a physician,for the treatment of moderate acne vulgaris with blue light. The desired dose is selected using the operator interface located on the front panel of the device. The PlasmaLux LS device delivers local area phototherapy, whereby lamps deliver the specified dose of Blue Light.

**Predicate Device Comparison:**

The PlasmaLuxLS is constructed in the same design configuration as the predicate devices, utilizing similar energy types and materials of identical composition. The light emitted by the PlasmaLux is of identical spectrum and power as that of the predicate devices. The PlasmaLux can be used with exactly the same treatment regimes as the predicate devices.

**Intended Use:**

The PlasmaLuxLS is a medical light source, which is intended for use for the treatment of moderate acne vulgaris with blue light.

**Performance Data:**

No Data Provided.

**Conclusion:**

On the basis of the information provided in this Summary, the Daavlin Distributing Company believes the PlasmaLuxLS is substantially equivalent to the legally commercialized predicate device.

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

The Daavlin Distributing Company
% Ms. Michele Thiel
205 West Bement Street
Bryan, Ohio 43506

NOV 2 4 2010

Re: K100628
Trade/Device Name: PlasmaLuxLS
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: ONE
Dated: October 26, 2010
Received: November 03, 2010

Dear Ms. Thiel:

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

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

K100628 Pg 1 of 1

## Indication for Use

NOV 2 4 2010

**510(k) Number**

**Device Name** PlasmaLuxLS

### Indications for Use

The PlasmaLuxLS is a medical laser device, which is intended for the treatment of moderate inflammatory acne vulgaris.

Prescription Use _X_ OR Over-the-Counter Use ___

(per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K100628