



Food and Drug Administration
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Silver Spring, MD 20993-0002

LIGHT SOURCES INCORPORATED

Ms. Susan Anthony-DeWet
FDA Listing Consultant
37 Robinson Boulevard
Orange, Connecticut 06477

December 17, 2015

Re: K151370

Trade/Device Name: UV Lamps for Indoor Tanning Devices
Regulation Number: 21 CFR 878.4635
Regulation Name: Sunlamp products and ultraviolet lamps intended
for use in sunlamp products
Regulatory Class: Class II
Product Code: LEJ
Dated: November 16, 2015
Received: November 20, 2016

Dear Ms. Anthony:

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 Parts 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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151370

Device Name

UV Lamps for Indoor Tanning Devices

Indications for Use (Describe)

This product is intended for the exclusive purpose of cosmetic tanning of the human skin using light between 260-400nm.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

K151370

This 510(k) summary is being submitted in accordance of the requirements of
21 CFR Part 807.92

Date Prepared May 15, 2015

1. Correspondent Information: AEGIS Regulatory, Inc. – Susan Anthony-DeWet
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On behalf of Sponsor: Light Sources, Inc.,
37 Robinson Boulevard, Orange, CT. 06477
Contact: Eugene Czako, Sales Engineer
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2. General Information:

2.1 Device: UV Lamps for Tanning

2.2 Regulation Description: Sunlamp products and ultraviolet lamps intended for use in sunlamp products.

2.3 Common/Usual Name: UV Sunlamp

2.4 Proprietary Names: Light Sources UV Lamps for Indoor Tanning Devices- Over 200+ Various Models (Master List included in submission contains models and Private Label names)

2.5 Classification: Class II

2.6 Classification Number: 878.4635

2.7 Product Code: LEJ

2.8 Performance Standard: 21 CFR 1040.20

2.9 Regulation Medical Specialty: General and Plastic Surgery

3. Device Description:

Light Sources UV Lamps for Indoor Tanning devices are ultraviolet lamps that have the same basic technological features and the same intended use. The ultraviolet sunlamps

in this submission are classified either as low pressure, or high pressure devices. The main difference for the various models of sunlamps in this submission are: lamp wattage, lamp length, lamp diameter, and spectral emissions.

Light Sources UV Lamps for Indoor Tanning devices are ultraviolet sunlamps classified either as low pressure, or high pressure devices emitting light between 260- 400nm.

The basic parts are as follows:

- Bases
- Glass Bulb (envelope)
- Electrodes (Cathodes/Coils)
- Phosphor Coating
- Reflector Coating
- Mercury
- Inert fill gases

4. Intended Use:

Light Sources UV Lamps for Indoor Tanning devices are intended for the exclusive purpose of cosmetic tanning of the human skin using light between 260- 400nm.

5. Predicate Device (s):

The proposed devices are substantially equivalent to the following predicate devices, which are currently in safe and effective commerce:

Primary Predicate Device: *All devices listed in Section I of this submission.

Secondary Predicate Devices:

1. UV Sunlamp 95 UF-11 Light Sources, Inc K901324 1990
2. UV Sunlamp 95 UF-11 Light Sources, Inc K883952 1988
3. UV Sunlamp 95 UF-11 Light Sources, Inc K874889 1987
4. UV Sunlamp 95 UF-11 Light Sources, Inc K870167 1987
5. UV Sunlamp 95 UF-11 Light Sources, Inc K854004 1985
6. UV Sunlamp 95 UF-11 Light Sources, Inc K853545 1985

*All of the devices included in this submission existed and were legally marketed prior to September 2, 2014. FDA accession numbers are included in this submission.

Federal Register Volume 79, Number 105 (Monday, June 2, 2014)] "Any sunlamp product or UV lamp intended for use in a sunlamp product legally marketed on or before September 2, 2014can be used as a predicate device in a 510(k)".

6. Substantial Equivalence to Predicate Device:

The reclassification order *Federal Register Volume 79, Number 105 (Monday, June 2, 2014)* (see *section N* under *FDA response 16*) states that “Any sunlamp product or UV lamp intended for use in a sunlamp product legally marketed on or before September 2, 2014can be used as a predicate device in a 510(k)”.

The primary predicate devices are identical to the proposed devices and no differences exist between the devices. The primary predicate devices existed and were legally marketed prior to September 2, 2014, a list of FDA accession numbers is included in this submission.

The secondary predicate devices differ from the proposed devices in that the proposed devices have additional safety features and newer components but have the same intended use as the secondary predicate devices; have the same technological characteristics as the secondary predicate devices and conform to the special controls required by the reclassification order.

After an analysis of the safety, indications, intended uses, performance features, design materials, chemical composition, energy source, 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 predicate device listed in section 5 of this summary.

7. Performance Data:

Light Sources UV Lamps for Indoor Tanning Devices have been tested and conforms to

INTERNATIONAL CONSENSUS STANDARDS:

- IEC/EN 61195:2014 (Double Capped Fluorescent Lamps Safety Specifications)
- IEC/EN 60355-2-27 (Household and Electrical Appliances Safety Requirements for Skin Exposure for UV and IR Radiation).

Light Sources UV Lamps for Indoor Tanning Devices have been tested under and are in compliance with

FDA PERFORMANCE STANDARDS:

- 21 CFR 1040.20 (Performance Standard For Sunlamp products and ultraviolet lamps intended for use in sunlamp products)

Specific performance testing (spectral analysis) data is submitted in this application for each device that measured irradiance to ensure compliance with radiation limits set out in 21 CFR 1040.20.

In addition to the standards above, Light Sources UV Lamps for Indoor Tanning Devices are designed and manufactured utilizing the following standards:

QUALITY SYSTEM:

- ISO 13485:2012 Medical Devices, Quality Management System
- ISO 9001:2008, Quality Management Systems

Conclusion

After an analysis of the safety, indications, intended uses, performance features, design materials, chemical composition, energy source, 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 predicate device(s) listed in section 5 of this summary. Therefore, substantial equivalency is requested.