DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Cosmedico Light, Inc.
Steven Schlitt
Director Of Engineering And Quality Assurance
233 Libbey Industrial Parkway
Weymouth, Massachusetts 02189

October 28, 2015

Re: K152095
Trade/Device Name: Ultraviolet Lamps Intended For Use In Sunlamp Products (commonly Known As "metal Halide Sunlamps")
Regulation Number: 21 CFR 878.4635
Regulation Name: Ultraviolet Lamp For Tanning
Regulatory Class: Class II
Product Code: LEJ
Dated: July 24, 2015
Received: July 28, 2015

Dear Steven Schlitt:

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 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" (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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152095

Device Name

Ultraviolet Lamps Intended for Use in Sunlamp Products (commonly known as "metal halide sunlamps")

Indications for Use *(Describe)*

INTENDED USE: This ultraviolet lamp is intended for use in sunlamp products for tanning of the human skin.

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.

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510(k) Summary

Per Sec. 807.92(c)

807.92(a)(1)

Date Prepared:	July 24, 2015
510(k) Company / Holder Name:	Cosmedico Light, Inc.
Contact Name:	Steven C. Schlitt
Title:	Director Engineering & Quality
Address:	233 Libbey Industrial Parkway Weymouth, MA 02189
Phone Number:	781-331-0949 (Ext. 107)
Fax Number:	781-331-4766

807.92(a)(2)

Device Proprietary Name:	Various Brands of Ultraviolet Lamps **See attachment F-1 for list of models and part numbers.**
Device Common or Usual Name:	Ultraviolet Sunlamps (Metal Halide Sunlamps)
Indication for Use / Intended Use	INTENDED USE: This ultraviolet lamp is intended for use in sunlamp products for tanning of the human skin.
Classification Name:	Sunlamp products and ultraviolet lamps intended for use in sunlamp products
Classification Code:	LEJ
Regulation Number:	21 CFR Part 878.4635
Device Classification	II

807.92(a)(3)

Predicate Devices:

Prior to September 2, 2014, the basic ultraviolet sunlamps named in this 510(k) existed and were offered for sale as legally marketed, **Class I, 510(k) exempt**, medical devices.

For the basis of this 510(k), Cosmedico Light claims substantial equivalence to these legally marketed devices. Since none of the ultraviolet lamps named in this 510(k) have changed in 1) intended use or 2) technological design characteristics after September 2, 2014, essentially the contemporary ultraviolet lamps are identical to the predicate devices (i.e., those basic sunlamps offered for sale prior to the FDA's cutoff date of Sept. 2, 2014).

Such an approach of using the legally marketed Class I medical devices as predicate devices is validated in the Final Reclassification Order published on June 2, 2014 in the Federal Register Vo. 79, No. 105, Page 31212 whereby it is stated that:

" FDA cleared several 510(k)s for sunlamp products prior to exempting the devices from premarket notification submission. At least one 510(k) for a sunlamp product has been cleared since then under product code LEJ. These cleared sunlamp products, as well as ***any 510(k)-exempt sunlamp product or UV lamp intended for use in a sunlamp product legally offered for sale on or before September 2, 2014, can serve as predicates for substantial equivalence purposes***."

It will be demonstrated in this 510(k) that the named ultraviolet lamps:

1) have the same intended use as the predicate devices
2) have the same technological characteristics as the predicate devices and
3) conform to the special controls required by the reclassification order

In short, the contemporary ultraviolet sunlamps of this 510(k) are as safe and as effective as the predicate devices.

Description of the Devices

This 510(k) applies to more 35 devices that fall into a generic class of ultraviolet lamps that have the same basic technological features and exactly the same intended use. The ultraviolet sunlamps of this 510(k) are classified scientifically as *high pressure, mercury-metal halide discharge devices.* The general lamp construction and technological principle of operation of all of the devices of this 510(k) is the similar to that of commonly used metal halide lamps used for

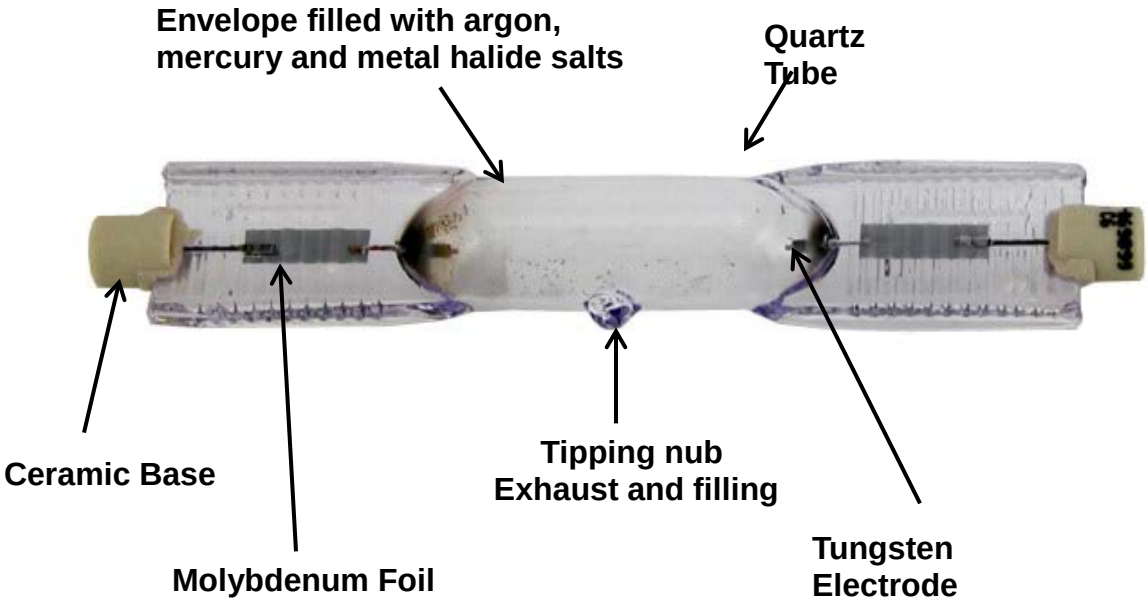
general lighting purposes. The main differentiators for the various sunlamps of this 510(k) include: lamp length, lamp diameter, lamp wattage, spectral characteristics and private labeling thereof.

The ultraviolet lamps named herein comprise a tubular quartz envelope, filled with an inert gas (such as argon) and a mixture of mercury and metal halide salts and sealed at both ends.

In principle the radiation created by the metal halide lamp is generated in the same way as in other discharge lamps. The main difference between these high pressure metal halide lamps and the low pressure discharge lamps also used as sunlamp products is in the main mechanism for production of the UV radiation. A low pressure sunlamp depends upon the conversion of short wavelength radiation inside the lamp envelope to higher wavelength radiation (UVA primarily) by a phosphor coating. The metal halide lamp (MHL) derives its radiation characteristics through the direct excitation of mercury and specific metal vapors that are created in the envelope during lamp run-up and stabilized operation. The selection of the particular metal halides, the fill gas composition, and the fill gas pressure are the main determinants of the UV output of the lamp. The physical construction: overall quartz length, diameter, and electrode spacing are variables that are design choices for the engineer in consideration of the lamp power and application requirements. However, it is the selection of the composition of the metallic salts dosed into the lamp envelope during manufacturing that is chief determinant of the spectral output of the lamp.

As with other components, the development of and final design of the metal halide sunlamp is quite dependent upon the application. Depending upon the UV requirements of the tanning equipment, a number of design components may be varied. One of the more critical application related determinants is the fixture design. Among the most critical aspects of the fixture are housing size, reflector type and shape and the cooling arrangement and capabilities. The existence of a myriad of MHL fixtures in the market has led to a wide variety of lamps with different power levels and basing options. MH lamps typically range in power ratings from about 250 W up to 1500 W. Additionally, the lamps come fitted with bases of three main types: Double Ended (clip-in or snap-in) technically named R7s, Single Ended (plug-in) with bases designated as GY9.5, and lamps with Wire Leads (also called cable terminations).

For illustrative purposes, the schematic below points out the main parts of a typical metal halide sunlamp:



Intended Use/Indications for Use

INTENDED USE: This ultraviolet lamp is intended for use in sunlamp products for tanning of the human skin.

Technological Characteristics

The technological characteristics of the ultraviolet sunlamps which are the subject of this 510(k) are identically the same as the technological characteristics of the predicate devices. The tables and data that are reported in Section 10 and the information summarized in Section 12, “Substantial Equivalence Discussion” of this 510(k), document that there are no significant differences between the contemporary and predicate devices. In fact, the subject/contemporary and the predicate devices are “one in the same”.

Performance Testing Summary

- All lamps are 100% tested for functionality at the end of the manufacturing process. Lamps that do not meet critical characteristics for functionality and safety are rejected.

- According to a Quality Sampling Plan, lamps are tested in-process and / or post-production for:

  - Electrical Characteristics and Safety
  - Mechanical Safety
  - Dimensional Integrity
  - Physical Design Attributes
  - UV radiation Characteristics, including:
    - UVA Irradiance
    - Erythemal Effective Irradiance
    - UVC/UVB ratio per 21 CFR 1040.20

As noted, the subject lamps of this 510(k) are identical to the predicate devices. Therefore, the subject lamps and the predicate devices have the same performance requirements.

Test (Performance Criteria)	Lamps meet criteria of predicate devices (Yes/No)
Functionality / Light up	Yes
Electrical Characteristics	Yes
Burn-in Behavior	Yes
Dimensional Characteristics	Yes
Mechanical Safety	Yes
Electrical Safety	Yes
UVA Irradiance	Yes
Erythemal Effective Irradiance	Yes
UVC/UVB Ratio (per 21 CFR1040.20)	Yes

TABLE F-1

COSMEDICO LIGHT
ULTRAVIOLET SUNLAMP PRODUCT RANGE
Metal Halide Lamp Types

Item Part Number	Description / Brand
900612555	ERGOLINE ULTRA 520W
913103645	CLEO HPA 1200 FX
913132641	CLEO HPA 250-500 / 30 SD L
913134045	CLEO HPA 250-500 SE FX
913137141	CLEO HPA 400 / 30 SD L
913138841	CLEO HPA 400 / 30 S L
919220245	CLEO HPA 400 S
919300145	CLEO HPA 400 / 30 SDC
920669541	CLEO HPA 700 S FX
920677041	CLEO HPA 250-500 / 30 SDC
938670245	CLEO HPA 1010 SE FX
996000101	ERGOLINE JK 60/80 EF
21104-1	JK-RUSA 400W R7s
21112-1	Cosmedico M 650W SE GY9.5
24003-1	Cosmedico M 400W R7s
24004-1	Cosmedico M 400W L
24006-1	Cosmedico M 500W SE
24008-1	Cosmedico M 500W L
24022-1	Cosmedico M 1000W SBSN GY 9.5
24103-1	Cosmedico M 1000W L
24171-1	Cosmedico M 1000W SE GY9.5
24178-1	Cosmedico M 800W R7s
R02362	Radiance HP 600-800W GY9.5
R02600	Radiance HP 1000-1400W L
R02606	Radiance HP 630W P
R02609	Radiance HP 300-520W GY9.5
R02610	Radiance HP 800-1000W GY9.5
R02611	Radiance HP 620W L
R02614	Radiance HP 600-650W GY9.5
R02615	Radiance HP 800-1000W GY9.5c
R03060	Radiance HP 400-500W R7s
SQ01400LWL	SUPRA Q-01400LWL
SQ01400WL	SUPRA Q-01400WL
SQ01400WL4	SUPRA Q-01400WL4
SQ03520PIJK	SUPRA Q-03520PIJK
SQ04500SI	SUPRA Q-04500SI
SQ0600PIGYL	SUPRA Q-0600PIGY-L
SQ06630R	SUPRA Q-06630R
SQ08100PIGYL	SUPRA Q-08100PIGY-L