



Food and Drug Administration
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Silver Spring, MD 20993-0002

Cosmedico Light Incorporated
Mr. Steven C. Schlitt
Director Engineering & Quality
233 Libbey Industrial Parkway
Weymouth, Massachusetts 02189

October 30, 2015

Re: K152273

Trade/Device Name: Cosmedico Ultraviolet Lamps of Various Models

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: August 15, 2015

Received: August 19, 2015

Dear Mr. 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 [SELECT ONE: Part 801 [or, for IVDs only] Parts 801 and 809]); 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)

Not used. K152273

Device Name

Cosmedico Ultraviolet Lamps of Various Models (intended for use in Sunlamp Products and commonly referred to as "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.

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

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510(k) Summary

Per Sec. 807.92(c)

807.92(a)(1)

Date Prepared:	August 10, 2015/ Revised 10-30-15
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:	Cosmedico Ultraviolet Lamps of Various Models <i>See attachment F-1 for list of models and part numbers.</i>
Device Common or Usual Name:	Ultraviolet 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. These devices are historically Over-the-Counter devices.

For the basis of this 510(k), Cosmedico Light claims substantial equivalence to these legally marketed OTC 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 OTC 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 than one hundred and sixty individual 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 *low pressure, mercury-rare gas discharge devices*. The general lamp construction and technological principle of operation of all of the devices of this 510(k) is the same as that of a common fluorescent lamp. 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 glass envelope, the internal surface of which is coated with a fluorescent phosphor. To each end of the tube, a glass mount is sealed. The main purpose of the mount is to provide 1) for a means of hermetically sealing the internal atmosphere of the tube, 2) a means of supporting an electrode and a means of 3) electrically accessing the internal atmosphere of the device via electrically conducting lead-wires. Once assembled as described, the envelope is evacuated of air, the air is replaced by an inert gas at a pressure significantly lower than that of the normal atmosphere, and a drop of mercury is injected into the enclosed envelope. Finally, the envelope is sealed.

In operation, the device, now called a "lamp", is connected to an electrical source typically in series with a ballast that provides for 1) ignition of a discharge through the inert-gas-mercury vapor mixture and 2) its subsequent stabilization and sustainment of the electrical behavior of the lamp. Once connected to the applied electric field, free electrons are accelerated through the mercury vapor wherein collisions take place with the mercury atoms. These collisions cause excitation of the electrons in the mercury (Hg) atom and the production of photons at various wavelengths. Certain of these photons travel to the bulb wall and excite the phosphor powder. The phosphor, in turn, emits radiation that is transmitted through the transparent glass envelope. The radiation that is emitted from a standard fluorescent general lighting lamp is primarily in the visible region of the spectrum (380nm-760nm). The radiation that is emitted from an ultraviolet sunlamp is primarily in the UV range of the electromagnetic spectrum (300nm-400nm). Modern day, low pressure ultraviolet sunlamps typically emit most of their energy in the wavelength range that is closest to the visible; that is, in the UVA range (320nm-400nm) range. The emission spectrum of sunlamps usually contains a relatively small proportion of UVB radiation. (260nm-320nm)

Some critical design components and aspects of the sunlamps include:

Glass Bulb (tubular envelope): Must be properly dimensioned and provides for transmission of ultraviolet energy in the range required for tanning.

Phosphor Powder: In addition to proper physical properties such as particle size and aqueous suspension compatibility, the phosphor must emit in the wavelength range required for a particular tanning application. It is the phosphor that primarily determines the spectral irradiance distribution of the radiation from the lamp.

Fill Gas and Pressure: The fill gas (in conjunction with the electrical control gear) determines the electrical characteristics of the lamp and has a large influence on the intensity of the radiation and the temporal depreciation of light output over the usage range.

Coated Electrodes (Cathodes / Coils): Provide a surface area for cathode coating and to a great extent influence starting of the lamp and its physical life.

Mercury: Mercury provides the basis for the operation of the lamp. It is through the excitation of mercury atoms and the subsequent quenching of the excited atoms in the vapor state that "light" is produced. It is the shortwave UV photons that resulting from the excitations that excite phosphor to produce light in a specific spectral range.

Bases: Allow the lamp to be installed in appropriate sockets for electrical connectivity to the electrodes.

For illustrative purposes:

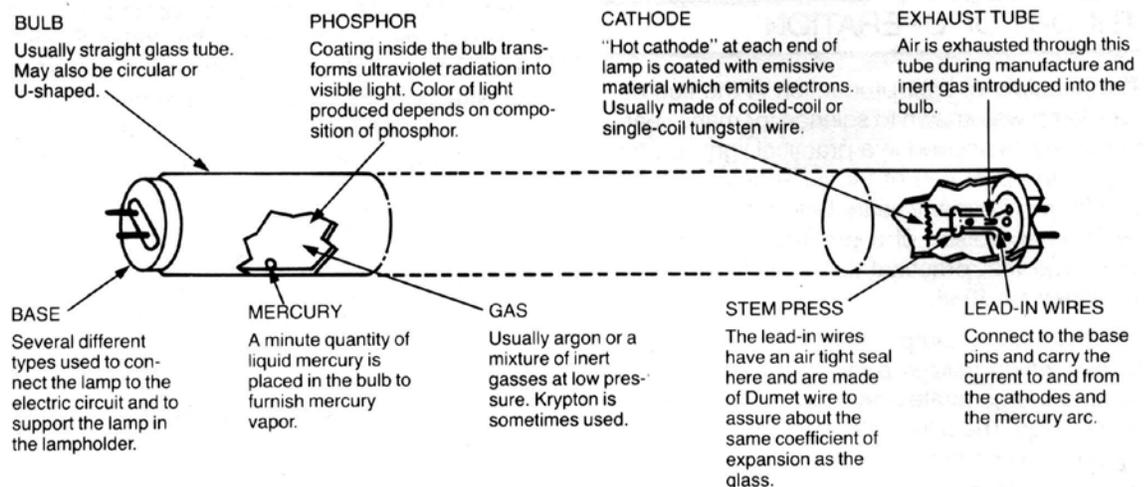


Figure 2. Basic parts of a typical hot cathode fluorescent lamp.

Intended Use/Indications for Use

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

TYPE OF USE: The predicate devices named in this 510(k) are historically used as Over the Counter (OTC) devices.

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 subject and predicate devices. In fact, the subject 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
 - Erythral 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
Physical Design (e.g., reflector angle)	Yes
UV Performance	Yes
UVA Irradiance	Yes
Erythral Effective Irradiance	Yes
UVC/UVB Ratio (per 21 CFR1040.20)	Yes

Lamps that do not meet Acceptance Criteria are either re-worked or scrapped.

ATTACHMENT F-1

COSMEDICO LIGHT, INC. ULTRAVIOLET SUNLAMP PRODUCT RANGE

COSMEDICO PART NUMBER	LAMP DESCRIPTION
10018	FR18T8 / COSMOLUX HRF
10036	F25WT5 / COSMOLUX LS
10044	F15WT5 / COSMOLUX X
10180	F59T12 / HI TAN / 80W
10186	F71T12 / Bermuda Gold Premium Plus / 105W
10187	F73T12 / Bermuda Gold / RDC / 105W
10198	F71T12 / HI TAN / 100W
10199	F73T12 / HI TAN / 100W / RDC
10201	F73T12 / EXPRESS TAN HO / 100W / RDC
10202	F73T12 / Genesis / 120W / RDC
10204	F71T12 / Genesis Hyperbronze / 105W
10205	F73T12 / Genesis Hyperbronze / 105W
10206	F72T12 / Genesis Plus / 105W
10212	F71T12 / Genesis / 120W
10217	F71T12 / Eternal Sun XPFT / 100W
10218	F73T12 / Eternal Sun XPFT / 100W / RDC
10219	F71T12 / Eternal Sun XP Gold / 100W
10220	F73T12 / Eternal Sun XP Gold / 100W / RDC
10222	F59T12 / Eternal Sun XP Gold / 80W
10224	F71T12 / Eternal Sun XP Gold / 120W
10318	FR18T8 / Sundash HRF
10330	F25T5 / UVA Plus
10331	F25T5 / COSMOLUX LS
10332	FR25WT5 / LSR
10990	F71T12 / COSMOLUX GSP 9K90 / 100W
10994	F71T12 / Eternal Sun XP Gold 9K90 / 100W
11282	F59T12 / GOLDARIUM SP / 80W
11305	F71T12 / GOLDARIUM SP / 100W
11306	F73T12 / GOLDARIUM SP / 100W
12482	F59T12 / COSMOSTAR LONGLIFE / 80W
12503	F71T12 / COSMOSTAR LONGLIFE / 100W
12600	F71T12 / COSMOLUX ESP / 100W
12601	F73T12 / COSMOLUX ESP / 100W / RDC
12607	F73T12 / Genesis GS 120W / RDC
15163	FR59T12 / Eternal Sun XP*R / 80W
15165	FR71T12 / Palm Beach Mega Tan S1-S2 / 100W
15211	FR59T12 / COSMOLUX VLR-TT / 80W / 220°
15212	FR71T12 / COSMOLUX VLR TT / 100 W
15214	FR71T12 / Bermuda Gold PLUS / 100W
15215	FR71T12 / COSMOSUN R / 100W
15216	FR71T12 / Eternal Sun XP*R / 100W
15220	FR79T12 / COSMOLUX VLR / 120W
15602	FR71T12 / COSMOLUX ESP-R / 100 W

ATTACHMENT F-1

COSMEDICO LIGHT, INC. ULTRAVIOLET SUNLAMP PRODUCT RANGE

COSMEDICO PART NUMBER	LAMP DESCRIPTION
15603	FR73T12 / COSMOLUX ESP / 100W / RDC
15640	FR71T12 / Genesis Super Power VHP15 Plus / 120W
15642	FR71T12 / Genesis Super Power VHP20 Plus / 120W
15649	FR71T12 / Genesis Hyperbronze / 105W
15656	FR71T12 / Bermuda Gold / Supreme 20 / 120W
15691	FR71T12 / /COSMOLUX VLR 9K-90 / 100W
15700	FR71T12 / COSMOLUX RA PLUS / 100W
15704	FR24T12 / COSMOLUX RA PLUS / 40W
15710	FR71T12 / COSMOLUX RCS / 100W
16077	F73T12 / HI TAN / VHO / RDC
16107	FR73T12 / COSMOLUX VHR-TT / 160W / RDC
16112	FR59T12 / COSMOLUX VHR-TT / 140W
16121	FR71T12 / Genesis 170WRS-E / 160W
16161	F71T12 / COSMOLUX / VHO
16169	FR71T12 / COSMOLUX VHR-TT / 160W
16172	F72T12 / HI TAN / VHO / RDC
16180	FR71T12 / COSMOLUX VHR / 160W
16202	FR75 T12 / COSMOLUX VHR 200 / 1.9 M
16211	FR75T12 / COSMOLUX VHR / HP / 180W
16218	FR71T12 / COSMOLUX VHR-200
16220	FR79T12 / COSMOLUX VHR 200 / 2.0 M
16223	FR79T12 / COSMOLUX 9K90 / 180W-200W
16234	FR79T12 / COSMOLUX 9K90 / 225W
16236	FR71T12 / COSMOSUN R / 160W
16238	FR79T12 / Ergoline Turbo Power / 200W
16239	FR74T12 / COSMOLUX VHR-TT / 160-200W
16250	FR79T12 / Suncapsule 250 MAX / 180-250W
16258	FR79T12 / Eternal Sun XP*r / 2.0M / 180-200W
16259	FR79T12 / Eternal Sun XP*R / 9K90 / 2.0M / 180-200W
16286	FR79T12 / COSMOLUX VHR HP 250 MAX / 180-250W
16307	FR72T12 / Genesis 170WRS / RDC
16317	FR73T12 / Express Tan VR 160W / RDC
16332	FR71T12 / COSMOLUX VHR / 200 / HP
16341	FR71T12 / Genesis Turbo Power VHP20 PLUS / 160W
16344	FR71T12 / Genesis Turbo Power VHP15 PLUS / 160W
16367	FR71T12 / Bermuda Gold Premium Plus / 160W
16385	FR71T12 / Ergoline Turbo Power VHP12 / 160W
16386	FR72T12 / Genesis GS 170W / RDC
16388	FR71T12 / HI-TAN / VHR / 160W
16391	FR71T12 / COSMOLUX VHR / 9K90 / 160W
16392	FR71T12 / Genesis 9K90 / 160WR
16393	FR71T12 / COSMOLUX VHR FLEX / 160-200W
16394	FR71T12 / COSMOLUX VHR-XT 160W

ATTACHMENT F-1

COSMEDICO LIGHT, INC. ULTRAVIOLET SUNLAMP PRODUCT RANGE

COSMEDICO PART NUMBER	LAMP DESCRIPTION
16395	FR71T12 / COSMOLUX VHR / HP / 160W
16398	FR71T12 / Genesis Hyperbronze / 170-200W
16399	FR71T12 / Suncapsule SCR 160 / 160W
16445	FR71T12 / Eternal Sun XP*R / 160W
16447	FR71T12 / Eternal Sun XP*R 9K90 /160W
16459	FR59T12 / Eternal Sun XP*R / 140W
16481	FR71T12 / Eternal Sun XP / 160W
16542	FR71T12 Eternal Sun XP HR 160W
18810	FR71T12 / COSMOLUX VLR.T / 100 W
21069	F25T5 / Radiance / 25W (07040)
21248	F72T12 / Radiance 8000 7.5 160W RDC (03017)
21249	F74T12 / Radiance 8.5 / 100-120W (07034)
21250	F72T12 / Radiance 7000 6.5 / 100-120W (03016)
21626	FR18T8 / Radiance HRF (07041)
22010	FR79T12 / Genesis VHP 20 / 120W
22015	FR79T12 / Genesis VHP 15 / 120W
22300	F73T12 / Radiance 120 / 120W / RDC (07044)
22302	F73T12 / Eternal Sun XP Gold / 120W
26111	F73T12 / FABUTAN /100W / RDC
26113	FR71T12 / Radiance 71i / 120W
26114	FR75T12 / Radiance 75i / 120W
26180	F71T12 / Radiance JAGUAR 10.0 / 100W (61747)
26189	FR71T12 / Silver Sun / 100W R
26190	F71T12 / Radiance 9000 8.5 / 100W (03011)
26191	F71T12 / Radiance 5K 5.0 / 100W (03001)
26192	F73T12 / Radiance 7000 RDC 6.5 / 100W (03006)
26193	F71T12 / Radiance 8000 7.5 / 100W (03009)
26194	F71T12 / Radiance PLUS 7000 6.5 / 100-120W (07011)
26195	F73T12 / Radiance 9000 8.5 / 100-120W / RDC (03012)
26196	FR73T12 / Radiance 7000 6.5 100W / RDC (03008)
26197	F73T12 / Millennium 7000 6.5 / 100W (03027)
26198	F73T12 / Radiance Plus 7000 6.5 / 100-120W (07013)
26199	F59T12 / Radiance 5000 / 5.0 / 80W (03000)
26202	F73T12 / Radiance +5000 5.0 / 100W (07003)
26203	FR73T12 / Radiance+5000 5.0 / 100-120W / RDC (07006)
26267	F73T12 / Radiance 8000 7.5 / 100-120W
26303	F71T12 / California Sun Ultra / 105W
26304	FR71T12 / California Sun Mega / 120W
26305	FR71T12 / California Sun Premier / 170W
26308	F71T12 / Radiance Black / 100W (03076)
26309	F73T12 / Radiance Black / 100-120W / RDC (03076)
26673	F73T12 / Radiance 8000 7.5 / 160W RDC (03018)
26682	FR71T12 / Radiance R2 XLP 1.7 / 100-120W (03100)

ATTACHMENT F-1

COSMEDICO LIGHT, INC. ULTRAVIOLET SUNLAMP PRODUCT RANGE

COSMEDICO PART NUMBER	LAMP DESCRIPTION
26774	FR71T12 / SilverSun / 160WR
27355	FR79T12 / Maxlight e-power XL / 200W-R
27450	FR71T12 / Radiance R2 / 100-120W / HOR 3.7 (07043)
27451	FR71T12 / Radiance R2 VHO R / 160-200W (07051)
27483	FR72T12 / Radiance R2 VHOR / 160-200W (07052)
27524	F73T12 / Radiance 5000 5.0 / RDC / 100W (03002)
27525	FR71T12 / Radiance 5000 5.0 / 100-120W (03003)
27526	F71T12 / Radiance 7000 6.5 / 100-120W (03005)
27527	FR71T12 / Radiance 7000 6.5 / 100-120W (03007)
27528	FR71T12 / Radiance Plus+ 7000 6.5 / 100-120W (07015)
27529	FR59T12 / Radiance R2 / 140W (07050)
27530	FR73T12 / Radiance R2 / 160-200W / RDC (07053)
27531	F59T12 / Radiance 7000 6.5 / 80W (03014)
27532	FR59T12 / Radiance Plus+ 6.5 / 80W (07014)
27533	FR59 / Radiance R2 3.7 / 80W (07042)
27534	FR71T12 / Palm Beach Mega Tan / 160W
27535	FR59T12 / Premium Plus Bermuda Gold Plus / 140W
27538	FR71T12 / Sundazzler Premium / 160W
27540	FR2.0M / Genesis GSXR 200 / 180W
27541	FR71T12 / Radiance R2 XLP 7.0 / 160W R (03098)
27548	FR79T12 / Radiance R2 / 2M / 120W (03081)
27574	FR74T12 / Eternal Sun XP*R / 200W / RDC
27712	FR73T12 / Radiance R2 3.7 / 100-120W (07045)
27728	F71T12 / Millennium 5000 5.0 / 100W (03021)
27733	FR72.2T12 / RadianceR2 VIP / FR71-RDC / 160W (07066)
27736	FR71T12 / GOLDARIUM SR / 100W
27748	FR79T12 / Eternal Sun BronzeR / 225W
27749	FR71T12 / Eternal Sun XP20R / 120W
27751	FR71T12 / Radiance Black / 100-120W (07075)
27756	FR71T12 / Radiance Black / 160W (07076)
27757	FR71T12 / Bermuda Gold / 100 W
28018	FR79T12 / Radiance R2 2M / 200W (03080)
28019	FR74T12 Radiance R3 VHOR / RDC / 200W (07048)
28021	F71T12/ Millennium 7000 6.5 / 100W (03026)
28022	FR71T12 / Radiance R2 Plus / 200W (07059)
28996	FR71T12 Millennium M2 3.15 / 160-180W (03087)
901935140	FR71T12 / Ergoline Super Power SR / 100W
926295040	FR71T12 / CLEO ADVANTAGE XPT / 160W-R
971036940	FR71T12 / CLEO ADVANTAGE / 100W-R