



Food and Drug Administration
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Silver Spring, MD 20993-0002

Wolff System Technology Corporation
% Mr. Steven Schlitt
Cosmedico Light Incorporated
233 Libbey Industrial Parkway
Weymouth, Massachusetts 01860

October 5, 2015

Re: K151841

Trade/Device Name: Wolff System Sunlams

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: July 2, 2015

Received: July 8, 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

Binita S. Ashar, M.D., M.B.A., F.A.C.S.

For Director

Division of Surgical Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151841

Device Name

Wolff System Sunlamps Intended for Use in Sunlamp Products (commonly referred to as "Ultraviolet Sunlamps")

Indications for Use (Describe)

INTENDED USE: Wolff System sunlamps are 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)

APPLICANT

Date Prepared:	July 2, 2015 / REVISED: Oct. 1, 2015
510(k) Company / Holder Name:	Wolff System Technology Corporation
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807.92(a)(2)

Wolff System Technology Corp., 980 Cobb Place Blvd. N.W. Suite 200, Kennesaw, GA 30144

Device Proprietary Name:	Wolff System Sunlamps See various brands in Attachment F-1
Device Common or Usual Name:	Ultraviolet Sunlamps
Indication for Use / Intended Use	INTENDED USE: Wolff System sunlamps are 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 (21 CFR 478.4635)
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), Wolff System 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 than one hundred and eighty 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:

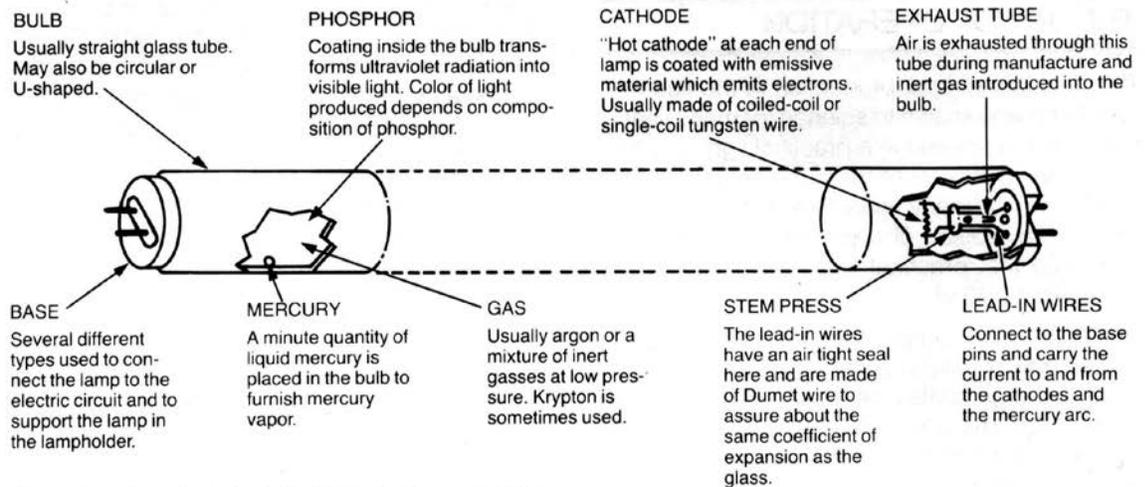


Figure 2. Basic parts of a typical hot cathode fluorescent lamp.

Intended Use/Indications for Use

INTENDED USE: Wolf System sunlamps are 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 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
 - 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
Physical Design (e.g., reflector angle)	Yes
UV Performance	Yes
UVA Irradiance	Yes
Erythemal Effective Irradiance	Yes
UVC/UVB Ratio (per 21 CFR1040.20)	Yes

Lamps that do not meet Acceptance Criteria are either re-worked, if technically feasible, or scrapped.

TABLE F-1

WOLFF SYSTEM TECHNOLOGY CORP. ULTRAVIOLET SUNLAMP PRODUCT RANGE

Wolff System PART NUMBER	LAMP DESCRIPTION
21015-0	F71T12 EURO BRONZE MAGNIFIER 7.0 PLUS 100W
21032-0	F71T12 SOLAR SERIES 1 6.5 PLUS 100W
21126-0	F71T12 VELOCITY EXTREME 100W
21143-0	F71T12 DARK TAN 100W
21144-0	F71T12 DARK TAN Plus 100W
21145-0	F71T12 DARK TAN II PLUS 100W
21146-0	F71T12 DARK TAN II 100W
21151-0	F71T12 ETERNAL SUN SX 100W
21154-0	F72T12 SOLARIUM VHO RDC
21155-0	F71T12 ETERNAL SUN HO 100W
21156-0	F71T12 ETERNAL SUN EX 100W
21158-0	F71T12 MERIDIAN BRONZER 100W
21160-0	F71T12 EURO BRONZE PRO MAG 7.0 PLUS 100W
21171-0	F71T12 VELOCITY PLUS 100W
21174-0	F71T12 DIAMOND SUN S 100W
21179-0	F72T12 DIAMOND SUN S 100W
21187-0	F71T12 VELOCITY 100W
21217-0	F71T12 SOLAR FLARE MAX 100W
21238-0	F72T12 HI SUN 9VK VHO
21239-0	F72T12 EUROBRONZE MAG 7.0 PLUS 160W RDC
21240-0	F59T12 MERIDIAN BRONZER 100W
21338-0	F71T12 SUN FUSION BL-FT 100W
21514-0	F71T12 DARK TAN ELITE 100W
21518-0	F71T12 XS BRONZING POWER 100W
21629-0	F71T12 DARQUE TAN 100W
22156-0	FR24T12 SOLARIUM LR 40W
22224-0	F73T12 BRONZING SUN PLUS 100W RDC
23001-0	F71T12 ETS ELITE ULTRA 120W
23002-0	F71 ETS ELITE WARM TONE 100W
23003-0	F71 ELITE COOL TONE 100W
23004-0	F71T12 ETS ELITE SELECT 100W
23005-0	F71T12 ELITE SELECT 120W
23006-0	F71T12 ELITE PLUS 100W
23007-0	F71T12 ETS ELITE PLUS 100W
23008-0	F71T12 X-POWER 100W
23009-0	F71T12 EURO SUN PLUS S3 100W
23010-0	FR71T12 ETS ELITE PLUS 100W
23011-0	FR71T12 ELITE PLUS 120W
23012-0	F71T12 EVERGLO PLUS 100W

Wolff System PART NUMBER	LAMP DESCRIPTION
23014-0	F71 X-POWER XP100W
23015-0	FR59T12 PRO TECH W Intensive R-UVA 80W
23016-0	FR71T12 PRO TECH W Intensive R-UVA 100W
23017-0	FR71T12 ORIGINAL SUN FLAGSHIP R PLUS 100W
23018-0	FR59T12 GOLDENBRONZE 140W
23019-0	F71T12 GOLDENBRONZE 100-120W
23020-0	FR71T12 ETS ELITE VZR 160W
23021-0	FR71T12 ELITE SELECT 160W
23022-0	FR71T12 ETS ELITE ULTRA 160W
23023-0	FR71T12 ELITE ULTRA 160W
23024-0	FR71T12 ETS ELITE JK90 160W
23025-0	FR71T12 ETS ELITE ULTRA 180-200W
23027-0	FR71 INFERNO 160X 160W
23028-0	F71T12 GOLDENBRONZE Maximum 100-120W
23029-0	F73T12 GOLDENBRONZE Maximum 100-120W RDC
23030-0	F71T12 GOLDENBRONZE VHO 160W
23031-0	FR79T12 ETS ELITE ULTRA / 200W
23032-0	FR79T12 ELITE ULTRA 200W
23033-0	FR79T12 GOLDENBRONZE 180-200W
23034-0	FR71T12 GOLDENBRONZE 100-120W
23035-0	FR73T12 GOLDENBRONZE 100W
23036-0	FR71T12 GOLDENBRONZE Plus 100-120W
23037-0	FR71T12 GOLDENBRONZE 160W
23038-0	FR71T12 GOLDENBRONZE Plus160W
23039-0	FR71T12 GOLDENBRONZE 200W
23040-0	F71T12 MASTER BRONZE 100-120W
23041-0	F73T12 ETS ELITE SELECT 120W
23042-0	FR75T12 PRO TECH W Intensive R-UVA 110W
23043-0	F71T12 GOLDENBRONZE Plus 100-120W
23044-0	F73T12 GOLDENBRONZE 100-120W RDC
23045-0	F71T12 GOLDENBRONZE II 100-120W
23046-0	F73T12 GOLDENBRONZE II 100-120W
23047-0	FR71T12 MASTER BRONZE 100-120W
23048-0	FR71T12 MASTER BRONZE 160W
23049-0	FR71T12 MASTER BRONZE 180-200W
23050-0	FR71T12 MASTER BRONZE Plus 160W
23051-0	F59T12 ETS ELITE 80W
23052-0	F59T12 GOLDEN BRONZE 80W
23053-0	FR59T12 GOLDEN BRONZE 80W
23054-0	F71T12 SUNFIRE 100W
23055-0	F71T12 SUNFIRE POWER WINDOW 100W
23056-0	FR79T12 ZOOM TAN VHO ZT 180W
23057-0	F71T12 SUNFIRE PLUS 100W
23060-0	FR75 SUNFIRE Intensive R-UVA 110W
23061-0	FR71 SUNFIRE Intensive R-UVA 100W

Wolff System PART NUMBER	LAMP DESCRIPTION
23074-0	F73T12 EVERGLO PLUS 100W RDC
23075-0	F73T12 EURO SUN PLUS S3 100W
23076-0	F73T12 DOMINION PLUS 100W RDC
23101-0	F25T5 D-Light
23102-0	F25T5 INFERNO
25984-0	F59T12 EURO BRONZE MAGNIFIER 7.0 PLUS 80W
25993-0	F59T12 VELOCITY 80W
25996-0	F71T12 SOLAR Rayz 100W
25999-0	F73T12 DARQUE TAN 100W
26000-0	FR71T12 BRONZING SUN PLUS 100W
26007-1	F71T12 INFERNO BL XP 100W
26015-0	F71T12 HOLLYWOOD TANS 42 100W
26022-0	F71T12 BRONZING SUN ULTRA 120W BiPin
26045-0	F71T12 BELLARIUM S 100W
26048-0	F73T12 BELLARIUM S 100W
26072-0	F73T12 VELOCITY 100W RDC
26094-0	F73T12 DARK TAN II 100W
26104-0	F73T12 ETERNAL SUN SX 100W
26127-0	FR71T12 DARKTAN II PLUS 100W
26128-0	F73T12 SOLARIUM VHO RDC
26129-0	F71T12 BRONZING SUN PLUS 100W
26133-0	F73T12 MERIDIAN BRONZER 100W RDC
26136-0	F73T12 DARQUE TAN PLUS 100W RDC
26138-0	F71T12 BRONZING SUN HPK90 100W
26140-0	F71T12 DOMINION PLUS 100W
26146-0	F73T12 DARK TAN II PLUS 100W
26157-0	F73T12 ETERNAL SUN EX 100W
26160-0	F71T12 HI SUN 9VK SOLAR SERIES-1 100W
26164-0	F73T12 EURO BRONZE PRO MAG 7.0 PLUS 100W
26166-0	F73T12 VELOCITY HI-WATT 120W
26263-0	F73T12 DARK TAN ELITE 100W RDC
26266-0	F73T12 XS BRONZING POWER 100W RDC
26268-0	F73T12 HI SUN 9VK VHO RDC
26269-0	F73T12 EUROBRONZE MAG 7.0 PLUS VHO-LT RDC
26271-0	F73T12 VELOCITY PLUS 100W
26277-0	FR71T12 ORIGINAL SUN 100W
26279-0	FR71T12 MERIDIAN BRONZER 100W
26293-0	F73T12 SOLAR SERIES-1 6.5 PLUS 100W RDC
26294-0	F73T12 MERIDIAN BRONZER 120W RDC
26606-0	FR59T12 BRONZING SUN 80W
26670-0	F71T12 VELOCITY SELECT 100W
26671-0	F71T12 VELOCITY SELECT PLUS 100W
27049-0	FR71T12 VELOCITY VS-R 160W
27066-0	FR79T12 BRONZING SUN GOLD 200W
27070-0	FR59T12 BRONZING SUN 140W

Wolff System PART NUMBER	LAMP DESCRIPTION
27083-0	FR79T12 BRONZING SUN 180W
27085-0	FR71T12 BRONZING SUN GOLD 200W
27086-0	F71T12 BRONZING SUN VHO
27110-0	FR73T12 SOLARIUM XLR 160W RDC
27111-0	FR72T12 SOLARIUM XLR 160W RDC
27112-0	FR71T12 BELLARIUM SR 160W
27123-0	FR71T12 BRONZING SUN HPK90 100W
27124-0	FR71T12 BRONZING SUN HP9K-90 PLUS 160W
27137-0	F71T12 MERIDIAN 160W
27172-0	FR71T12 BRONZING SUN HPK90 160W
27173-0	FR71T12 BRONZING SUN HPK90 200W
27176-0	FR71T12 BRONZING SUN HP9K90 180W
27177-0	FR71T12 CELSIUS 160W
27197-0	FR71T12 HT 60/54 II 160W VHO-LT
27202-0	FR73T12 BRONZING SUN 160W RDC
27205-0	FR71T12 ORIGINAL SUN 160W LT
27206-0	FR71T12 ORIGINAL SUN PLUS 160W LT
27207-0	FR71T12 ORIGINAL SUN 9VK 160W
27208-0	F73T12 HI SUN 9VK 100W RDC
27209-0	FR71T12 MERIDIAN BRONZER 160W LT
27211-0	FR71T12 DARQUE TAN 160W LT
27215-0	FR71T12 VELOCITY ULTRA 180W BiPin
27221-0	FR71T12 BRONZING SUN 160W
27223-0	FR71T12 BRONZING SUN PLUS 160W
27224-0	FR73T12 BRONZING SUN PLUS 160W RDC
27226-0	FR71T12 ETERNAL SUN UXR 160W
27248-0	FR71T12 BRONZING SUN MAG 100W
27251-0	FR71T12 BRONZING SUN 100W
27261-0	FR73T12 BRONZING SUN 100W RDC
27282-0	FR73T12 ORIGINAL SUN 160W LT
27466-0	F71 SUN FUSION BL-CC 100W
28006-0	FR79T12 ORIGINAL SUN VHO
28007-0	FR59T12 ORIGINAL SUN 140W LT
29434-0	FR73T12 BRONZING SUN ELITE 160W RDC LT
29881-0	FR71T12 SOLAR RAYZ 160W LT
29889-0	FR71T12 BRONZING SUN ELITE 160W LT
901756240	LET RIO-BRONZE-R 71"
901768540	LET GOLDEN SUN-HO-71"
901770840	LET RIO R HO F71
902920640	LET GOLDEN SUN PLUS RHO 71"
902924440	LET GOLDEN SUN PLUS HO 73"
902926840	LET GOLDEN SUN PLUS HO 71"
903302940	LET F71T12 3.3 HO 100W
903302940	LET F71T12 3.3 HO 100W
926295040	CLEO Advantage 160W-R XPT

Wolff System PART NUMBER	LAMP DESCRIPTION
961232840	CLEO Advantage 808 100W-R
961234240	CLEO Advantage 808 100W
963369927	CLEO Compact S 25W R
971036940	CLEO Advantage 100W-R
971646027	CLEO Compact 15W
986566340	CLEO Advantage 100W
986568740	CLEO Advantage 100W F73T12 S
986571740	CLEO Swift 80W R
996000064	LET RIO Bronze SHR 160W 71
996000160	LET RIO Plus SHR 71