



Food and Drug Administration
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September 16, 2015

JK HOLDING GmbH
Juergen Gerstenmeier
Official Correspondent
Koehlershohner Strasse 60
53578 Windhagen
Germany

Re: K151400

Trade/Device Name: Ergoline, Sun Angel, Soltron, Sundash and Palm Beach Tan
Sunlamp Products
Regulation Number: 21 CFR 878.4635
Regulation Name: Ultraviolet lamp for tanning
Regulatory Class: Class II
Product Code: LEJ
Dated: August 14, 2015
Received: August 18, 2015

Dear Gerstenmeier:

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" (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
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Center for Devices and
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Enclosure

Indications for Use

510(k) Number (if known)

K151400

Device Name

Ergoline, Sun Angel, Soltron, Sundash and Palm Beach Tan Sunlamp Products

Indications for Use (Describe)

This sunlamp product is intended exclusively for cosmetic tanning of the human skin, for one person at a time, at the age of 18 or above.

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.

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510(k) Summary of Safety and Effectiveness

In accordance with the requirements of the Safe Medical Device Act, JK Holding GmbH herewith submits a Summary of Safety and Effectiveness. This 510(k) summary for the Ergoline, Soltron, Sun Angel, Sundash and Palm Beach Tan private label sunlamp products meets the requirements of 21 CFR 807.92

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Date Prepared: August 12th, 2015

Device(s) Identification:

Device trade name: Ergoline sunlamp products
Common name: Ergoline sunlamp products

The following table presents the Ergoline sunlamp products in comparison to Soltron private label devices.

The basic products can be upgraded with the conversion kit to Soltron private label sunlamp products.

The Ergoline, Soltron, Sun Angel, Sundash or Palm Beach Tan private label sunlamp products contain the same basic products, which are the technical fundament for different product lines. The conversion kit only serves to label the basic product as a Soltron or Palm Beach Tan private label sunlamp product. It does not alter any technical specification or aspect of the devices.

Model-No.:	Ergoline sunlamp products:	Conversion Kit / Private Label:
JK 103 / 34-3	Ergoline/PASSION 34/3 Super Power	XS-40 KISS
JK 103 / 40-3	Ergoline/PASSION 40/3 Turbo Power (WHITE)	S-45 FLIRT
JK 103 / 40-3	Ergoline/PASSION 40/3 Turbo Power (BLACK)	S-45 FLIRT
JK 103 / 40-3 AC	Ergoline/PASSION PLUS 40/3 Turbo Power (WHITE)	S-45 FLIRT+AC
JK 103 / 40-3 AC	Ergoline/PASSION PLUS 40/3 Turbo Power (BLACK)	S-45 FLIRT+AC
JK 98 / 48-0	Ergoline/SUNRISE 480 Turbo Power	V-55 UNIVERSE
JK 98 / 48-0	Ergoline/SUNRISE 480 Turbo Power (Sound & Ambient Light)	V-55 UNIVERSE
JK 70 / 0-30	Ergoline/ Open Sun 1050	XXL-95 SHARK
JK 155 / 46-3 AC	Ergoline/AFFINITY 700 Advanced Performance	L-70 BUTTERFLY
JK 155 / 46-3	Ergoline/AFFINITY 700 Advanced Performance	L-70 BUTTERFLY
JK 155 / 50-4 TT	Ergoline/AFFINITY 900 Advanced Performance	XL-85 WILDCAT
JK 116 / 48-0	Ergoline/ ESSENCE 48 SMART POWER (Grey)	V-50 SPACE CAB
JK 127 / 48-4 TT	Ergoline/Prestige 1000 Intelligent Performance	XXL-115 STARLIGHT
JK 127 / 52-4 TT	Ergoline/Prestige 1400 Intelligent Performance	XXL-125 EAGLE
JK 126 / 38-3 AC	Ergoline/Inspiration 500 Smart Performance	M-55 RACER
JK 126 / 42-4 AC	Ergoline/Inspiration 600 Dynamic Performance	M-60 JUMP
JK 92 / 43-3	Ergoline/AFFINITY 500 Turbo Power	-
JK 92 / 46-3-AC	Ergoline/AFFINITY 600 Turbo Power Air Condition	-
JK 92 / 51-4 TT	Ergoline/AFFINITY 800 Turbo Power Temptronic	-
JK 116 / 48-0	Ergoline/ ESSENCE 48 SMART POWER (Red)	-
JK 116 / 48-0	Ergoline/ ESSENCE 48 SMART POWER (PBT)	-
JK 127 / SS 48-4-TT	Ergoline/Sun Select 1000 Intelligent Performance	-

Model-No.:	Ergoline sunlamp products:	Conversion Kit / Private Label:
JK 127 / SS 52-4 TT	Ergoline/Sun Select 1400 Intelligent Performance	-
JK 103 / 34-0	Ergoline / Passion 34 Super Power (20 min)	-
JK 103 / 34-0	Ergoline / Passion 34 Super Power (15 min)	-
JK 103 / 32-0	Ergoline/ Flair 32 Super Power (20 min)	-
JK 103 / 32-0	Ergoline/ Flair 32 Super Power (15 min)	-
JK 103 / 32-1	Ergoline/ Flair 32/1 Super Power (20 min)	-
JK 103 / 32-1	Ergoline/ Flair 32/1 Super Power (15 min)	-
JK 103 / 32-3	Ergoline/ Flair 32/3 Super Power (15 min)	-
JK 103 / 32-3	Ergoline/ Flair 32/3 Super Power (20 min)	-

Device trade name: Sun Angel sunlamp products
Common name: Sun Angel sunlamp products

The following table presents the Sun Angel sunlamp products (no conversion kits).

Model-No.:	Sun Angel sunlamp products:
JK 103 / SA 40-3 AC	SUNANGEL 400
JK 127 / SA 52-4 TT	SUN ANGEL DUO 1400 (12 min)
JK 127 / SA 52-4 TT	SUN ANGEL DUO 1400 (15 min)
JK 126 / SA 42-4 AC	SUN ANGEL DUO 600 (20 min)
JK 126 / SA 42-4 AC	SUN ANGEL DUO 600 (15 min)
JK 100 / SA 52-4 TT	Sun Angel S 52 (20 min)
JK 100 / SA 52-4 TT	Sun Angel S 52 (15 min)
JK 104 / SA 46-3 TT	Sun Angel S 46
JK 132 / SA 52-4 TT	Sun Angel Duo S 52 (20 min)
JK 132 / SA 52-4 TT	Sun Angel Duo S 52 (15 min)

Device trade name: Soltron sunlamp products
Common name: Soltron sunlamp products

The following table presents the Soltron sunlamp products (no conversion kits).

Model-No.:	Soltron sunlamp products:
JK 103 / 32-0	Soltron/XXS-30 Super Power (Mango Tango)
JK 79 / 52-4 TT	Soltron/ XXL-110 DYNAMIC POWER (Blueberry Blue)
JK 79 / 48-4 TT	Soltron/ XL-80 DYNAMIC POWER (Magic Melon)
JK 103 / 34-3	Soltron/ Coco Cabana XXS-35

Device trade name: Sundash sunlamp products
Common name: Sundash sunlamp products

The following table presents the Sundash sunlamp products in comparison to Soltron private label devices.

The basic products can be upgraded with the conversion kit to Soltron private label sunlamp products.

The Ergoline, Soltron, Sun Angel, Sundash or Palm Beach Tan private label sunlamp products contain the same basic products, which are the technical fundament for different product lines. The conversion kit only serves to label the basic product as a Soltron or Palm Beach Tan private label sunlamp product. It does not alter any technical specification or aspect of the devices.

Model-No.:	Ergoline sunlamp products:	Conversion Kit / Private Label:
JK 103 / 32-0	SUNDASH 32 Super Power	XXS-35 SURF
JK 103 / 32-1	SUNDASH 32/1 Super Power (15 min)	XXS-35 SURF
JK 103 / 32-1	SUNDASH 32/1 Super Power (20 min)	XXS-35 SURF

Device trade name: Palm Beach Tan sunlamp products
Common name: Palm Beach Tan sunlamp products

The following table presents the Palm Beach Tan sunlamp products (no conversion kits).

Model-No.:	Ergoline sunlamp products:
JK 103 / 32-0	Palm Beach Tan / SIGNATURE

Classification of the device:

Device Classification Name: Booth, Sun Tan
Product Code: LEJ
C.F.R. Section.: 878.4635
Classification Panel: General & Plastic Surgery
Device Class: Class II

Device Description:

The primary technical components of sunlamp products are artificial sources of UV radiation and a mechanical structure.

Different UV sources intensities with characteristic UV-A and UV-B proportions result in cosmetic tanning of the human skin.

The UV-A proportion primarily generates a superficial tan, which appears rapidly and is intensive but also fades more rapidly. The UV-B radiation is primarily responsible for more long-term tanning results.

Intended Use:

This sunlamp product is intended exclusively for cosmetic tanning of the human skin, for one person at a time, at the age of 18 or above.

Predicate devices:

All proposed devices are currently listed as Class I devices (510(k) exempt sunlamp product) and are legally offered for sale before September 2, 2014. In accordance with the final order these devices are used as predicate devices for substantial equivalence purposes.

Model No.	Conversion Kit	Brand and type name	Body Lamps	Watts	High Pressure Face	Watts	UV-B facial lamps	Watts	Shoulder Lamps	Watts	Max. exposure time [min]
JK 116 / 48-0	-	Ergoline/ ESSENCE 48 SMART POWER	48	200	N/A	N/A	N/A	N/A	N/A	N/A	9
JK 126 / 38-3 AC	Soltron/M-55 RACER	Ergoline/Inspiration 500 Smart Performance	38	160/180	3	400	2	8	N/A	N/A	12
JK 126 / 42-4 AC	Soltron/M-60 JUMP	Ergoline/Inspiration 600 Dynamic Performance	42	200	4	400	3	8	N/A	N/A	12
JK 126 / SA 42-4 AC	-	SUN ANGEL DUO 600	42	200	4	400	3	8	N/A	N/A	20
JK 126 / SA 42-4 AC	-	SUN ANGEL DUO 600	42	200	4	400	3	8	N/A	N/A	15
JK 127 / 48-4 TT	Soltron/XXL-115 STARLIGHT	Ergoline/Prestige 1000 Intelligent Performance	48	200	4	500	3	8	2	240	10
JK 127 / 52-4 TT	Soltron/XXL-125 EAGLE	Ergoline/Prestige 1400 Intelligent Performance	52	200	4	520	3	8	2	240	10
JK 127 / SA 52-4 TT	-	SUN ANGEL DUO 1400	52	200	4	520	3	8	2	240	12
JK 127 / SA 52-4 TT	-	SUN ANGEL DUO 1400	52	200	4	520	3	8	2	240	15
JK 127 / SS 48-4-TT	-	Ergoline/Sun Select 1000 Intelligent Performance	48	200	4	500	3	8	2	240	10
JK 127 / SS 52-4 TT	-	Ergoline/Sun Select 1400 Intelligent Performance	52	200	4	520	3	8	2	240	10
JK 155 / 46-3	Soltron/L-70 BUTTERFLY	Ergoline/AFFINITY 700 Advanced Performance	46	160	3	500	2	8	7	25	12

Model No.	Conversion Kit	Brand and type name	Body Lamps	Watts	High Pressure Face	Watts	UV-B facial lamps	Watts	Shoulder Lamps	Watts	Max. exposure time [min]
JK 155 / 46-3 AC	Soltron/L-70 BUTTERFLY	Ergoline/AFFINITY 700 Advanced Performance	46	160	3	500	2	8	7	25	12
JK 155 / 50-4 TT	Soltron/XL-85 WILDCAT	Ergoline/AFFINITY 900 Advanced Performance	50	160	4	520	3	8	7	25	12
JK 70 / 0-30	Soltron/XXL-95 SHARK	Ergoline/ Open Sun 1050	27	580	3	640	N/A	N/A	N/A	N/A	12
JK 79 / 48-4 TT	-	Soltron/ XL-80 DYNAMIC POWER	48	200	4	520	N/A	N/A	2	240	10
JK 79 / 52-4 TT	-	Soltron/ XXL-110 DYNAMIC POWER	52	200	4	520	3	8	2	240	10
JK 92 / 43-3	-	Ergoline/AFFINITY 500 Turbo Power	43	160	3	500	N/A	N/A	7	25	12
JK 92 / 46-3-AC	-	Ergoline/AFFINITY 600 Turbo Power Air Condition	46	160	3	500	N/A	N/A	7	25	12
JK 92 / 51-4 TT	-	Ergoline/AFFINITY 800 Turbo Power Temptronic	50	160	4	520	N/A	N/A	7	25	12
JK 98 / 48-0	Soltron/V-55 UNIVERSE	Ergoline/SUNRISE 480 Turbo Power	48	200	N/A	N/A	N/A	N/A	N/A	N/A	9
JK 98 / 48-0	Soltron/V-55 UNIVERSE	Ergoline/SUNRISE 480 Turbo Power	48	200	N/A	N/A	N/A	N/A	N/A	N/A	9
JK 116 / 48-0	-	ESSENCE 48 10 MN PBT	48	160	N/A	N/A	N/A	N/A	N/A	N/A	10
JK 100 / SA 52-4 TT	-	Sun Angel S52 20 min (with Sensor 3)	52	200	4	520	3	8	2	240	20
JK 100 / SA 52-4 TT	-	Sun Angel S52 15 min (with Sensor 3)	52	200	4	520	3	8	2	240	15
JK 104 / SA 46-3 TT	-	Sun Angel S46 20 min (with Sensor 3)	46	200	3	520	2	8	7	25	20
JK 132 / SA 52-4 TT	-	Sun Angel Duo S52 20 min (with Sensor 3)	52	200	4	520	3	8	2	240	20

Model No.	Conversion Kit	Brand and type name	Body Lamps	Watts	High Pressure Face	Watts	UV-B facial lamps	Watts	Shoulder Lamps	Watts	Max. exposure time [min]
JK 132 / SA 52-4 TT	-	Sun Angel Duo S52 15 min (with Sensor 3)	52	200	4	520	3	8	2	240	15
JK 103 / 34-0	-	Passion 34/0 20 min	34	120	N/A	N/A	N/A	N/A	N/A	N/A	20
JK 103 / 34-0	-	Passion 34/0 15min	34	120	N/A	N/A	N/A	N/A	N/A	N/A	15
JK 103 / 32-0	-	Flair 32/0 20 min	32	120	N/A	N/A	N/A	N/A	N/A	N/A	20
JK 103 / 32-0	-	Flair 32/0 15 min	32	120	N/A	N/A	N/A	N/A	N/A	N/A	15
JK 103 / 32-1	-	Flair 32/1 20 min	32	120	1	400	N/A	N/A	N/A	N/A	20
JK 103 / 32-1	-	Flair 32/1 15 min	32	120	1	400	N/A	N/A	N/A	N/A	15
JK 103 / 32-3	-	Flair 32/3 15 min	32	120	3	400	N/A	N/A	N/A	N/A	15
JK 103 / 32-3	-	Flair 32/3 20 min	32	120	3	400	N/A	N/A	N/A	N/A	20
JK 103 / 34-3	-	Coco Cabana XXS-35 34/3 15min	34	120	3	400	2	8	N/A	N/A	15

Summary of performed tests:

The proposed devices have been tested in respect to biocompatibility in accordance with the ISO 10993-series, electrical and mechanical safety in accordance with IEC 60601-1 (IEC 60335-2-27 and UL482) and EMC in accordance with IEC 60601-1-2 (CISPR 14-1 and 14-2).

The spectral emission of all sunlamp products was measured. The test procedure for measuring the spectral emission is in accordance with IEC 60335-2-27.

The irradiance ratio limits of all proposed sunlamp products are in accordance with 21 CFR 1040.20 (c) (1). The maximum timer intervals and exposure schedules have been determined according to FDA's "policy on maximum timer interval and exposure schedule for sunlamp products"

Conclusion:

JK Holding GmbH believes that the Ergoline, Soltron, Sun Angel, Sundash and Palm Beach Tan private label sunlamp products are substantially equivalent to currently legally marketed devices. Also all Special Controls as demanded by the Final Order are fulfilled. These devices do not introduce new indications for use, have the same technological characteristics and do not introduce new potential hazards or safety risks.