Chapter 5

510(k) Summary

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 Sunrise 7200 Hybrid Technology and their further private label sunlamp products meets the requirements of 21 CFR 807.92

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Date Prepared: April 8th, 2019

Device(s) Identification:

Device trade name: Ergoline Sunrise 7200 Hybrid Technology
Common name: Sunlamp product

The following table presents the different variants of the Ergoline Sunrise 7200 Hybrid Light Technology / Hybrid Technology sunlamp product.
All variants use the same basic device technology and differ only in effect lighting, comfort features and private labelling. All variants use the hybrid light technology.

Model-No.:	Variant Name:
JK 158 / 48-0 HT	Ergoline Sunrise 7200 Hybrid Light Technology Planet Fitness Sound/ Bluetooth
JK 158 / 48-0 HT VS	Ergoline Sunrise 7200 Hybrid Light Technology Planet Fitness Sound / Bluetooth / Vibra Shape
JK 158 / 48-0 HT	Ergoline Sunrise 7200 Hybrid Technology / Sound/ Bluetooth
JK 158 / 48-0 HT VS	Ergoline Sunrise 7200 Hybrid Technology Sound / Bluetooth / Vibra Shape

The basic products can be upgraded with conversion kits, consisting of stickers with the private label naming, to Soltron, Palm Beach Tan or further private label sunlamp products.
The conversion kit only serves to label the basic product as a Soltron, Palm Beach Tan or further private label sunlamp product. It does not alter any technical specification or aspect of the devices.

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 as well as a mechanical structure with a defined active surface.
UV lamps emit different UV-A and UV-B proportions of the UV radiation. The UV-A proportion primarily generates a superficial tan, which appears rapidly and is intensive but also fades more rapidly. UV-B radiation is primarily responsible for more long-term tanning results.
The Ergoline Sunrise 7200 Hybrid Light Technology / Hybrid Technology provides tanning results by combining traditional UV light with red light in a synergistic combination of light spectra.

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

Legally Marketed Predicate device:

Device Name:	Sunrise 6200 and Sunrise 7200
Model No.:	JK 158 / 48-0 and JK 158 / 48-0 VS
510k number:	K173565
Device Classification Name:	Booth, Sun Tan
Product Code:	LEJ
C.F.R. Section.:	878.4635
Classification Panel:	General & Plastic Surgery
Device Class:	Class II

Comparison to predicate device:

The following table presents the comparison of technological characteristics, functions and parameters of the identified predicate device and the proposed devices.

Parameter	**Proposed device JK 158 / 48-0 HT JK 158 / 48-0 HT VS**	**Predicate device JK 158 / 48-0 JK 158 / 48-0 VS**	**Evaluation**
Intended Use/Indications for Use	This sunlamp product is intended exclusively for aesthetic tanning of the human skin, for one person at a time, at the age of 18 or above.	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.	Identical
Number of body lamps	48 (34 UV lamps and 14 UV+Red Light lamps)	48 (all UV lamps)	Similar: The irradiance characteristics are comparable. The safety has been confirmed additionally by corresponding tests in accordance with IEC 62471. In terms of functionality and safety there is no impact due to this difference.
Watts	200	200	Identical

Parameter	Proposed device JK 158 / 48-0 HT JK 158 / 48-0 HT VS	Predicate device JK 158 / 48-0 JK 158 / 48-0 VS	Evaluation
Lamp item description	GENESIS Type U Hybrid Performance - 200 W (UV light) and GENESIS Type R Hybrid Performance - 200 W (Mix of UV+Red Light)	GENESIS VHP9 Smart Performance 200 W	Similar: The irradiance characteristics are comparable. The safety has been confirmed additionally by corresponding tests in accordance with IEC 62471. In terms of functionality and safety there is no impact due to this difference
Number of Beauty Light LEDs	60 (3x20)	none	The irradiance characteristics are comparable. The safety has been confirmed additionally by corresponding tests in accordance with IEC 62471. In terms of functionality and safety there is no impact due to this difference.
Watts	45 (3x15)	none	No impact (see above)
Max exposure time [min]	9	9	Identical
Electrical requirements	230V 3Ø or 230V 2Ø	230V 3Ø or 230V 2Ø	Identical
Total power consumption [Watts]	10600	9500	Similar: The power is higher due to the use of different electronic lamp ballasts. Performance is not impaired.

Parameter	Proposed device JK 158 / 48-0 HT JK 158 / 48-0 HT VS	Predicate device JK 158 / 48-0 JK 158 / 48-0 VS	Evaluation
Rated overcurrent protection device (circuit breaker)	40A / 3-pole 3Ø or 70A / 2-pole 2Ø	40A / 3-pole 3Ø or 70A / 2-pole 2Ø	identical.
Number of wires	4 3Ø or 3 2Ø	4 3Ø or 3 2Ø	identical
Irradiance ratio in accordance with 1040.20	fulfilled	fulfilled	identical
Electrical safety	IEC 60601-1	IEC 60601-1	identical
Electromagnetic compatibility	IEC 60601-1-2	IEC 60601-1-2	identical

Summary of performance testing:
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 and EMC in accordance with IEC 60601-1-2.
The proposed devices are in compliance with U.S. performance standard 21CFR 1040.20

Conclusion:
JK Holding GmbH believes that the proposed devices are substantially equivalent to the legally marketed predicate device. Also, all Special Controls are fulfilled. The proposed devices do not introduce new indications for use, have the same technological characteristics and do not introduce new potential hazards or safety risks.