JK Holding GmbH
Juergen Gerstenmeier
Director Research & Development
Koehlershohner Strasse 60
Windhagen, 53578 De

October 11, 2018

Re: K180555
Trade/Device Name: Ergoline Prestige 1600 Hybrid Performance
Regulation Number: 21 CFR 878.4635
Regulation Name: Ultraviolet lamp for tanning
Regulatory Class: Class II
Product Code: LEJ
Dated: August 7, 2018
Received: August 14, 2018

Dear Juergen 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Neil R Ogden -S
2018.10.11 08:49:06 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180555

Device Name
Ergoline Prestige 1600 Hybrid Performance

Indications for Use *(Describe)*
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.

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 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 Prestige 1600 Hybrid Performance meets the requirements of 21 CFR 807.92

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Date Prepared: September 07th, 2018

Device(s) Identification:

Device trade name:	Ergoline Prestige 1600 Hybrid Performance
Common name:	Sunlamp product
Model No.:	JK 162 / 52-4 TT HP

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.

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.

Predicate device:

Device Name:	Ergoline/Prestige 1400 Intelligent Performance
510k number:	K151400
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 device.

Parameter	**Predicate device** Ergoline/Prestige 1400 Intelligent Performance	**Proposed device** Ergoline Prestige 1600 Hybrid Performance	**Evaluation**
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.	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	52 (all UV lamps)	52 (38 UV lamps, 14 UV+red light lamps)	Similar: The irradiance characteristics are still comparable as provided under section 18. 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
Lamp item description	GENESIS VHP10 Intelligent Performance - 200 W	GENESIS Type U Hybrid Performance - 200 W (UV light) GENESIS Type R Hybrid Performance - 200 W (red light)	Similar: The irradiance characteristics are still comparable as provided under section 18. The safety has been confirmed additionally by corresponding tests in accordance with IEC 62471. In terms of

Parameter	**Predicate device** Ergoline/Prestige 1400 Intelligent Performance	**Proposed device** Ergoline Prestige 1600 Hybrid Performance	**Evaluation**
			functionality and safety there is no impact due to this difference
Number of High Pressure Facial lamps	4	4	Identical
Watts	520	520	Identical
Lamp item description	Ergoline Ultra 520W	Ergoline Ultra 520W	Identical
Filter	Ultra Performance 412	Ultra Performance 412	Identical
Number of UV-B Facial lamps	3	3	Identical
Watts	8	8	Identical
Lamp item description	Genesis VHP B-Power E9 8W	Genesis Type R Hybrid 8W	Similar
Number of Shoulder lamps	2	2	Identical
Watts	240	240	Identical
Lamp item description	Ergoline Ultra 250W	Ergoline Ultra 250W	Identical
Filter	Ultra Performance 912	Ultra Performance 912	Identical
Max exposure time [min]	10	10	identical
Electrical requirements	230V 3Ø or 230V 2Ø	230V 3Ø or 230V 2Ø	identical
Total power consumption [watts]	18,500 W	17,600 W	Similar: less power consumption due to the use of electronic ballasts instead of magnetic ballasts. Performance is not impaired.
Rated overcurrent protection device (circuit breaker)	70A / 3-pole 3Ø or 100A / 2-pole 2Ø	70A / 3-pole 3Ø or 100A / 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 (max. 0.003)	fulfilled	fulfilled	identical (refer to section 18 for bench test reports)

Parameter	**Predicate device** Ergoline/Prestige 1400 Intelligent Performance	**Proposed device** Ergoline Prestige 1600 Hybrid Performance	**Evaluation**
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 device has 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 device is in compliance with U.S. performance standard 21CFR 1040.20.
All proposed sunlamp products are in compliance with U.S. performance standard 1040.20.

Conclusion:
JK Holding GmbH believes that the Ergoline Prestige 1600 Hybrid Performance is substantially equivalent to currently legally marketed devices. Also all special controls are fulfilled. This device does not introduce new indications for use, has the same technological characteristics and does not introduce new potential hazards or safety risks.