JK-Holding GmbH
Juergen Gerstenmeier
Executive Director Research & Development
Koehlershohner Strabe 60
Windhagen, 53578 DE

May 10, 2019

Re: K190173
Trade/Device Name: Ergoline Inspiration 550 Hybrid Technology / Sound, Ergoline Inspiration 550 Hybrid Technology / AC / Sound, Ergoline Planet Fitness 42/4 Hybrid Light Technology / Sound
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: April 24, 2019
Received: April 26, 2019

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,

For Jennifer Stevenson,
Acting Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K190173

Device Name
Ergoline Inspiration 550 Hybrid Technology
Ergoline Planet Fitness 42/4 Hybrid Light Technology

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 Inspiration 550 Hybrid Technology / Ergoline Planet Fitness 42/4 Hybrid Light Technology and their further private label sunlamp products meets the requirements of 21 CFR 807.92

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Date Prepared: April 18th, 2019

Device(s) Identification:

Device trade name: Ergoline Inspiration 550 Hybrid Technology
Ergoline Planet Fitness 42/4 Hybrid Light Technology
Common name: Sunlamp product

The following table presents the different variants of the Ergoline Inspiration 550 Hybrid Technology / Ergoline Planet Fitness 42/4 Hybrid Light 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 126 / 42-4 HT	Ergoline Inspiration 550 Hybrid Technology / Sound
JK 126 / 42-4 HT AC	Ergoline Inspiration 550 Hybrid Technology / AC / Sound
JK 126 / 42-4 HT	Ergoline Planet Fitness 42/4 Hybrid Light Technology / Sound

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. The UV-B radiation is primarily responsible for more long-term tanning results.
Traditional UV light with the addition of (beauty) red light results in a natural looking tan.
Optimal tanning results are achieved due to the 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:	Ergoline Inspiration 600 Dynamic Performance
Model No.:	JK 126 / 42-4 AC
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 devices.

Parameter	**Proposed device JK 126 / 42-4 HT JK 126 / 42-4 HT AC**	**Predicate device JK 126 / 42-4 AC**	**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	42 (28 UV lamps and 14 UV+Red Light lamps)	42 (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.

Parameter	Proposed device JK 126 / 42-4 HT JK 126 / 42-4 HT AC	Predicate device JK 126 / 42-4 AC	Evaluation
Watts	Canopy: 160 Bench: 180	200	Similar: The lamp wattage is less with the proposed device due to the use of different electronic lamp ballasts and a more efficient lamp-ballast system.
Lamp item description	Canopy: GENESIS Type U Hybrid Performance 160 W (UV light) and GENESIS Type R Hybrid Performance - 160 W (Mix of UV+Red Light) Bench: GENESIS Type U Hybrid Performance 180 W (UV light) and GENESIS Type R Hybrid Performance - 180 W (Mix of UV+Red Light)	GENESIS VHP12 Dynamic Power 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 High Pressure Facial lamps	4	4	Identical
Watts	400	400	Identical
Lamp item description	Ergoline Ultra 520W	Ergoline Ultra 520W	Identical
Filter	Ultra Performance 862H	Ultra Performance 862H	Identical
Number of Low Pressure Facial lamps	3	3	Identical
Watts	8	8	Identical

Parameter	**Proposed device JK 126 / 42-4 HT JK 126 / 42-4 HT AC**	**Predicate device JK 126 / 42-4 AC**	**Evaluation**
Lamp item description	Genesis Type R Hybrid 8W (Mix of UV+Red Light)	Genesis VHP B-Power E9 8W	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
Electrical requirements	230V 3Ø or 230V 2Ø	230V 3Ø or 230V 2Ø	Identical
Total power consumption [Watts]	11200	13200	Similar: The total power consumption is less with the proposed device due to the use of different electronic lamp ballasts. The irradiance characteristics are comparable.
Number of wires	4 3Ø or 3 2Ø	4 3Ø or 3 2Ø	Identical
Max exposure time	12	12	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.