



July 1, 2022

JK-Holding GmbH  
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Re: K220500

Trade/Device Name: Ergoline Vitality Total Light 3, Planet Fitness 50/4 TLT by Ergoline, Planet Fitness 42/3 TLT by Ergoline, Ergoline Vitality Hybrid Light 3, Ergoline Vitality Hybrid Light, Planet Fitness 50/4 HLT by Ergoline, Planet Fitness 46/3 HLT by Ergoline, Ergoline Vitality Pure Light 3, Ergoline Vitality Pure Light, Planet Fitness 50/4 PLT III by Ergoline, Planet Fitness 50/4 PLT by Ergoline, Planet Fitness 46/3 PLT by Ergoline, Planet Fitness 42/3 PLT by Ergoline

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: May 20, 2022

Received: May 31, 2022

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); 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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jianting Wang  
Acting Assistant Director  
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and Infection Control Devices  
Office of Product Evaluation and Quality  
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Enclosure

## Indications for Use

510(k) Number (if known)

K220500

Device Name

Ergoline Vitality Total Light, Ergoline Vitality Hybrid Light, Ergoline Vitality Pure Light, Planet Fitness TLT by Ergoline, Planet Fitness HLT by Ergoline, Planet Fitness PLT by Ergoline

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.**

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# **Chapter 5**

## **510(k) Summary of Safety and Effectiveness**

# **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 includes the bundles for device trade names for Ergoline Vitality Total Light, Ergoline Vitality Hybrid Light, Ergoline Vitality Pure Light, Planet Fitness TLT by Ergoline, Planet Fitness HLT by Ergoline, Planet Fitness PLT by Ergoline & variant units which meet the requirements of 21 CFR 807.92

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**Device trade name:** Ergoline Vitality Total Light 3  
Planet Fitness 50/4 TLT by Ergoline  
Planet Fitness 42/3 TLT by Ergoline  
Ergoline Vitality Hybrid Light 3  
Ergoline Vitality Hybrid Light  
Planet Fitness 50/4 HLT by Ergoline  
Planet Fitness 46/3 HLT by Ergoline

Ergoline Vitality Pure Light 3  
Ergoline Vitality Pure Light  
Planet Fitness 50/4 PLT III by Ergoline  
Planet Fitness 50/4 PLT by Ergoline  
Planet Fitness 46/3 PLT by Ergoline  
Planet Fitness 42/3 PLT by Ergoline

**Date Prepared:** February 16<sup>th</sup>, 2022

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## 1.1 Device(s) Identification:

In the following, 5 different bundles of devices will be presented and evaluated.

Bundle No	Model No	Device names
1	JK 164 / 42-3 TLT-3 AC JK 164 / 42-3 TLT-3 JK 164 / 42-3 TLT AC JK 164 / 42-3 TLT	Planet Fitness 42/3 TLT by Ergoline Ergoline Vitality Total Light 3
2	JK 164 / 42-3 PLT AC JK 164 / 42-3 PLT	Planet Fitness 42/3 PLT by Ergoline Ergoline Vitality Pure Light
3	JK 164 / 50-4 TLT-3 TT JK 164 / 50-4 TLT-3 JK 164 / 50-4 HLT-3 TT JK 164 / 50-4 HLT-3 JK 164 / 50-4 TLT TT JK 164 / 50-4 TLT AC JK 164 / 50-4 TLT	Planet Fitness 50/4 TLT by Ergoline Ergoline Vitality Total Light 3 Planet Fitness 50/4 HLT by Ergoline Ergoline Vitality Hybrid Light 3
4	JK 164 / 50-4 PLT-3 AC JK 164 / 50-4 PLT-3 JK 164 / 50-4 PLT AC JK 164 / 50-4 PLT	Planet Fitness 50/4 PLT III by Ergoline Ergoline Vitality Pure Light 3 Planet Fitness 50/4 PLT by Ergoline Ergoline Vitality Pure Light
5	JK 164 / 46-3 PLT AC JK 164 / 46-3 PLT JK 164 / 46-3 HLT AC JK 164 / 46-3 HLT	Planet Fitness 46/3 PLT by Ergoline Ergoline Vitality Pure Light Planet Fitness 46/3 HLT by Ergoline Ergoline Vitality Hybrid Light

All products have an identical intended use and comparable technology.

The different devices in the bundles have different trade names, number of lamps, a different combination of light spectra and different maximum exposure times.

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

For further information concerning conversion kits please refer to chapter 11.

### 1.1.1 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.

### 1.1.2 Classification of all proposed 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



## 1.2 Device trade names of bundle 1:

Planet Fitness 42/3 TLT by Ergoline  
Ergoline Vitality Total Light 3

Common name: Sunlamp product

The following table presents the different variants of the JK 164 / 42-3 Total Light Technology sunlamp product.

All variants use the same basic device technology and differ only in private labelling, exterior design, decor lighting and comfort features.

Model-No.	Variant Name
JK 164 / 42-3 TLT-3 AC JK 164 / 42-3 TLT-3	Planet Fitness 42/3 TLT by Ergoline
	Ergoline Vitality Total Light 3
JK 164 / 42-3 TLT AC JK 164 / 42-3 TLT	Planet Fitness 42/3 TLT by Ergoline
	Ergoline Vitality Total Light 3

### 1.2.1 Device Description:

#### Total Light Technology

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.

Using traditional UV light with the combination of red and blue light the user indulges in a new luxurious tanning experience.

Optimal tanning results are achieved due to the synergistic combination of light spectra.

### 1.2.2 Legally marketed predicate device:

Device Name: Planet Fitness 42/4 Hybrid Light Technology  
510k number: K190173  
Device Classification Name: Booth, Sun Tan  
Product Code: LEJ  
C.F.R. Section.: 878.4635  
Classification Panel: General & Plastic Surgery  
Device Class: Class II

**Legally marketed technical referenced device:**

Device Name:	Sunrise 7200 Hybrid Light Technology
510k number:	K183539
Device Classification Name:	Booth, Sun Tan
Product Code:	LEJ
C.F.R. Section.:	878.4635
Classification Panel:	General & Plastic Surgery
Device Class:	Class II

### 1.2.3 Comparison bundle 1 to predicate device:

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

Parameter	Proposed device	Proposed device	Predicate device 1	Technically referenced device	Evaluation to predicate device	Evaluation to Technically referenced device
Model-No.	JK 164 / 42-3 TLT-3 AC JK 164 / 42-3 TLT-3	JK 164 / 42-3 TLT AC JK 164 / 42-3 TLT	JK 126 / 42-4 HT AC	JK 158 / 48-0 HT	N/A	N/A
Intended 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 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 aesthetic tanning of the human skin, for one person at a time, at the age of 18 or above	N/A	Identical	N/A
Number of body lamps	42 (28 UV lamps and 14 UV + Red Light lamps)	42 (28 UV lamps and 14 UV + Red Light lamps)	42 (28 UV lamps and 14 UV + Red Light lamps)	N/A	Identical	N/A
Watts of body lamps	200W	160W	canopy 160W bench 180W	N/A	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.	N/A

Parameter	Proposed device	Proposed device	Predicate device 1	Technically referenced device	Evaluation to predicate device	Evaluation to Technically referenced device
Lamp item description	GENESIS PLT Pure Light Technology 200W GENESIS HLT Hybrid Light Technology 200W (UV&Red light)	GENESIS PLT Pure Light Technology 160W GENESIS HLT Hybrid Light Technology 160W (UV&Red light)	GENESIS Type U Hybrid Performance 160 W / 180W GENESIS Type R Hybrid Performance 160W / 180W	N/A	Different description, no impact, see above.	N/A
Number of Total Light-LED	72 LED (36 Red + 36 Blue)	36 LED (18 RED + 18 Blue)	N/A	60 Red LED	N/A	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 of Total Light-LED	100W	50W	N/A	45W	N/A	No impact, see above.

Parameter		Proposed device	Proposed device	Predicate device 1	Technically referenced device	Evaluation to predicate device	Evaluation to Technically referenced device
UV-Facials	Number of UV-facials	3 x 42 UVA-LED	3 x 42 UVA-LED	4 high pressure lamps	N/A	Similar, the irradiance characteristics are still comparable as provided under section 18. In terms of functionality and safety there is no impact due to this difference.	N/A
	Watts facial lamp	3 x 80W	3 x 80W	4x400W	N/A	No impact, see below.	N/A
	Facial item description	Spectra UV-LED	Spectra UV-LED	High pressure lamp Ergoline Ultra 520W	N/A	Similar, the irradiance characteristics are still comparable as provided under section 18. In terms of functionality and safety there is no impact due to this difference.	N/A
	Filter facial lamps	N/A	N/A	Ultra Performance 862H	N/A	No filters necessary due to no use of high-pressure lamps.	N/A
	Number of low pressure facial lamps	2 x HLT	2 x HLT	3 x Type R	N/A	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.	N/A

Parameter		Proposed device	Proposed device	Predicate device 1	Technically referenced device	Evaluation to predicate device	Evaluation to Technically referenced device
	Watts low pressure facial lamp	8W	8W	8W	N/A	Identical	N/A
	Low pressure facial lamps item description	GENESIS HLT Hybrid Light Technology 8W	GENESIS HLT Hybrid Light Technology 8W	Genesis Type R Hybrid 8W (Mix of UV+Red Light)	N/A	Different description, no impact, see above.	N/A
Max exposure time [min]		12 minutes	12 minutes	12 minutes	N/A	Identical	N/A
Electrical Requirements		230V 3Ø or 230V 2Ø	230V 3Ø or 230V 2Ø	230V 3Ø or 230V 2Ø	N/A	Identical	N/A
Total power consumption [watts]		11,600 W (with AC) 10,400 (w/o AC)	8,800 W (with AC) 7,200 W (w/o AC)	11,200 W	N/A	Similar: The power is different due to different lamps. Performance is not impaired.	N/A
Rated overcurrent protection device (circuit breaker)		45A / 3-pole or 80 A /2-pole (with AC) or 45A / 3-pole or 70A /2-pole (w/o AC)	35 A / 3-pole or 60 A / 2-pole (with AC) 30A / 3-pole or 50A/ 2-pole (w/o AC)	70A / 3-pole 3Ø or 100A / 2-pole 2Ø	N/A	Similar, the overcurrent protection is less with the proposed device due to the use of LED technology for facials and different lamps. The irradiance Characteristics are still comparable as provided under section 18.	N/A
Number of wires		4 3Ø or 3 2Ø	4 3Ø or 3 2Ø	4 3Ø or 3 2Ø	N/A	Identical	N/A
Irradiance ratio in accordance with 1040.20		fulfilled	fulfilled	fulfilled	N/A	Identical (refer to section 18 for bench test reports)	N/A
Parameter		Proposed device	Proposed device	Predicate device 1	Technically referenced device	Evaluation to predicate device	Evaluation to Technically referenced

						<b>device</b>
Electrical safety	IEC 60601-1	IEC 60601-1	IEC 60601-1	N/A	Identical	N/A
Electromagnetic compatibility	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	N/A	Identical	N/A

#### 1.2.4 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.

#### 1.2.5 Conclusion:

JK-Holding GmbH believes that the JK 164 / 42-3 Total Light Technology are substantially equivalent to currently legally marketed devices. Also, all special controls are fulfilled. These devices do not introduce new indications for use, has the same technological characteristics and does not introduce new potential hazards or safety risks.

### 1.3 Device trade names of bundle 2:

Planet Fitness 42/3 PLT by Ergoline  
Ergoline Vitality Pure Light

Common name: Sunlamp product

The following table presents the different variants of the JK 164 / 42-3 Pure Light Technology sunlamp product.

All variants use the same basic device technology and differ only in private labelling, exterior design, decor lighting and comfort features.

Model-No.	Variant Name
JK 164 / 42-3 PLT AC	Planet Fitness 42/3 PLT by Ergoline
JK 164 / 42-3 PLT	Ergoline Vitality Pure Light

#### 1.3.1 Device description:

##### Pure Light Technology

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

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.



**1.3.2 Legally marketed predicate device 2:**

Device Name:	Planet Fitness 42/4
510k number:	K151400 CV344_PF_100003421_V01
Device Classification Name:	Booth, Sun Tan
Product Code:	LEJ
C.F.R. Section.:	878.4635
Device Class:	Class II

### 1.3.3 Comparison bundle 2 to predicate device:

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

Parameter		Proposed device	Predicate device	Evaluation to predicate device
Model-No.		JK 164 / 42-3 PLT AC JK 164 / 42-3 PLT	JK 126 / 42-4	N/A
Intended 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 aesthetic tanning of the human skin, for one person at a time, at the age of 18 or above	Identical
Number of body lamps		42 UV lamps	42 UV lamps	Identical
Watts of body lamps		160W	200 W	Similar, the irradiance characteristics are still comparable as provided under section 18. In terms of functionality and safety there is no impact due to this difference.
Lamp item description		GENESIS PLT Pure Light Technology 160W	GENESIS VHP12 Dynamic Power 200W	Different description, no impact, see above.
UV-Facials	Number of UV-facials	3 x 42 UVA-LED	4 high pressure lamps	Similar, the irradiance characteristics are still comparable as provided under section 18. In terms of functionality and safety there is no impact due to this difference.
	Watts facial lamp	3 x 80W	4 x 400W	No impact, see below.
	Facial item description	Spectra UV-LED	High pressure lamp Ergoline Ultra 520W	Similar, the irradiance characteristics are still comparable as provided under section 18. In terms of functionality and safety there is no impact due to this difference.

Parameter		Proposed device	Predicate device	Evaluation to predicate device
UV-Facials	Filter facial lamps	N/A	Ultra Performance 862	No filters necessary due to no use of high-pressure lamps.
	Number of low pressure facial lamps	2 x PLT	3 x Type U	Similar, the irradiance characteristics are still comparable as provided under section 18. In terms of functionality and safety there is no impact due to this difference.
	Watts low pressure facial lamp	8W	8W	Identical
	Low pressure facial lamps item description	GENESIS PLT Pure Light Technology 8W	Genesis VHP B-Power E9 8W	Different description, no impact, see above.
Max exposure time [min]	12 minutes	12 minutes	Identical	
Electrical Requirements	230V 3Ø or 230V 2Ø	230V 3Ø or 230V 2Ø	Identical	
Total power consumption [watts]	9,000 W (with AC) 7,800 W (w/o AC)	13,200W	Similar, the total power consumption is less with the proposed device due to the use of LED technology for facials and different lamps. The irradiance characteristics are still comparable as provided under section 18.	
Rated overcurrent protection device (circuit breaker)	35 A / 3-pole or 60 A / 2-pole (with AC) 30A / 3-pole or 50A/ 2-pole (w/o AC)	70A / 3-pole 3Ø or 100A / 2-pole 2Ø	Similar, die overcurrent protection is less with the proposed device due to the use of LED technology for facials and different lamps. The irradiance characteristics are still comparable as provided under section 18.	
Number of wires	4 3Ø or 3 2Ø	4 3Ø or 3 2Ø	Identical	
Irradiance ratio in accordance with 1040.20	fulfilled	fulfilled	Identical (refer to section 18 for bench test reports)	
Electrical safety	IEC 60601-1	IEC 60601-1	Identical	
Electromagnetic compatibility	IEC 60601-1-2	IEC 60601-1-2	Identical	

#### 1.3.4 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.

#### 1.3.5 Conclusion:

JK-Holding GmbH believes that the JK 164 / 42-3 Pure Light Technology are substantially equivalent to currently legally marketed devices. Also, all special controls are fulfilled. These devices do not introduce new indications for use, has the same technological characteristics and does not introduce new potential hazards or safety risks.

### 1.4 Device trade names of bundle 3:

Planet Fitness 50/4 TLT by Ergoline  
Ergoline Vitality Total Light 3  
Planet Fitness 50/4 HLT by Ergoline  
Ergoline Vitality Hybrid Light 3

Common name: Sunlamp product

The following table presents the different variants of the JK 164 / 50-4 Total Light Technology and JK 164 / 50-4 Hybrid Light Technology sunlamp product.

All variants use the same basic device technology and differ only in private labelling, exterior design, decor lighting, combination of light spectra and comfort features.

Model-No.	Variant Name
JK 164 / 50-4 TLT-3 TT	Planet Fitness 50/4 TLT by Ergoline
JK 164 / 50-4 TLT-3	Ergoline Vitality Total Light 3
JK 164 / 50-4 HLT-3 TT	Planet Fitness 50/4 HLT by Ergoline
JK 164 / 50-4 HLT-3	Ergoline Vitality Hybrid Light 3
JK 164 / 50-4 TLT TT	Ergoline Vitality Total Light 3
JK 164 / 50-4 TLT AC	Planet Fitness 50/4 TLT by Ergoline
JK 164 / 50-4 TLT	Ergoline Vitality Total Light 3

#### 1.4.1 Device description:

##### Total Light Technology

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. Using traditional UV light with the combination of red and blue light the user indulges in a new luxurious tanning experience. Optimal tanning results are achieved due to the synergistic combination of light spectra.

### **Hybrid Light Technology**

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.

#### **1.4.2 Legally marketed predicate device:**

Device Name:	Ergoline Prestige 1600 Hybrid Technology
510k number:	K180555
Device Classification Name:	Booth, Sun Tan
Product Code:	LEJ
C.F.R. Section.:	878.4635
Classification Panel:	General & Plastic Surgery
Device Class:	Class II

#### **Legally marketed technical referenced device:**

Device Name:	Sunrise 7200 Hybrid Light Technology
510k number:	K183539
Device Classification Name:	Booth, Sun Tan
Product Code:	LEJ
C.F.R. Section.:	878.4635
Classification Panel:	General & Plastic Surgery
Device Class:	Class II

### 1.4.3 Comparison bundle 3 to predicate device:

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

Parameter	Proposed device	Proposed device	Proposed device	Proposed device	Predicate device	Technically referenced device	Evaluation to predicate device	Evaluation to Technically referenced device
Model-No.	JK 164 / 50-4 TLT-3 TT JK 164 / 50-4 TLT-3	JK 164 / 50-4 HLT-3 TT JK 164 / 50-4 HLT-3	JK 164 / 50-4 TLT TT	JK 164 / 50-4 TLT AC JK 164 / 50-4 TLT	JK 162 / 52-4 TT HP	JK 158 / 48-0 HT	N/A	N/A
Intended 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 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 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 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 aesthetic tanning of the human skin, for one person at a time, at the age of 18 or above	N/A	Identical	N/A

Parameter	Proposed device	Proposed device	Proposed device	Proposed device	Predicate device	Technically referenced device	Evaluation to predicate device	Evaluation to Technically referenced device
Number of body lamps	50 (36 UV lamps + 14 UV+Red Light lamps)	50 (36 UV lamps + 14 UV+Red Light lamps)	50 (36 UV lamps + 14 UV+Red Light lamps)	50 (36 UV lamps + 14 UV+Red Light lamps)	52 (38 UV lamps and 14 UV+Red Light lamps)	N/A	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.	N/A
Watts of body lamps	200W	200W	160W	160W	200 W	N/A	Identical	N/A
Lamp item description	GENESIS PLT Pure Light Technology 200W GENESIS HLT Hybrid Light Technology 200W (UV&Red light)	GENESIS PLT Pure Light Technology 200W GENESIS HLT Hybrid Light Technology 200W (UV&Red light)	GENESIS PLT Pure Light Technology 160W GENESIS HLT Hybrid Light Technology 160W (UV&Red light)	GENESIS PLT Pure Light Technology 160W GENESIS HLT Hybrid Light Technology 160W (UV&Red light)	GENESIS Type U Hybrid Performance GENESIS Type R Hybrid Performance (UV & Red light)	N/A	Different description, no impact, see above.	

Parameter	Proposed device	Proposed device	Proposed device	Proposed device	Predicate device	Technically referenced device	Evaluation to predicate device	Evaluation to Technically referenced device
Number of Total Light-LED	108 LED (54 Red + 54 Blue)	90 Red LED	36 LED (18 RED + 18 Blue)	36 LED (18 RED + 18 Blue)	N/A	60 Red LED	N/A	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 of Total Light-LED	150W	120W	50W	50W	N/A	45W	N/A	No impact, see below.



Parameter		Proposed device	Proposed device	Proposed device	Proposed device	Predicate device	Technically referenced device	Evaluation to predicate device	Evaluation to Technically referenced device
UV-Facials	Number of UV-facials	4 x 42 UVA-LED	4 x 42 UVA-LED	4 x 42 UVA-LED	4 x 42 UVA-LED	4 high pressure lamps	N/A	Similar, the irradiance characteristics are still comparable as provided under section 18. In terms of functionality and safety there is no impact due to this difference.	N/A
	Watts facial lamp	4 x 80W	4 x 80W	4 x 80W	4 x 80W	4 x 520 W	N/A	No impact, see below.	N/A
	Facial item description	Spectra UV-LED	Spectra UV-LED	Spectra UV-LED	Spectra UV-LED	High pressure lamp Ergoline Ultra 520W	N/A	Similar, the irradiance characteristics are still comparable as provided under section 18. In terms of functionality and safety there is no impact due to this difference.	N/A
	Filter facial lamps	N/A	N/A	N/A	N/A	Ultra Performance 412	N/A	No filters necessary due to no use of high pressure lamps.	N/A

Parameter		Proposed device	Proposed device	Proposed device	Proposed device	Predicate device	Technically referenced device	Evaluation to predicate device	Evaluation to Technically referenced device
UV-Facials	Number of low pressure facial lamps	4 x HLT	4 x HLT	4 x HLT	4 x HLT	3 x Type R	N/A	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.	N/A
	Watts low pressure facial lamp	8W	8W	8W	8W	8 W	N/A	Identical	N/A
	Low pressure facial lamps item description	GENESIS HLT Hybrid Light Technology 8W	GENESIS HLT Hybrid Light Technology 8W	GENESIS HLT Hybrid Light Technology 8W	GENESIS HLT Hybrid Light Technology 8W	Genesis Type R Hybrid 8W	N/A	Different description, no impact, see above.	

Parameter		Proposed device	Proposed device	Proposed device	Proposed device	Predicate device	Technically referenced device	Evaluation to predicate device	Evaluation to Technically referenced device
Shoulder Tanner	Number of Shoulder lamps	2 x 20 UVA-LED	2 x 20 UVA-LED	2 x 20 UVA-LED	2 x 20 UVA-LED	2 high pressure lamps	N/A	Similar, the irradiance characteristics are still comparable as provided under section 18. In terms of functionality and safety there is no impact due to this difference.	
	Watts of shoulder lamps	2 x 40W	2 x 40W	2 x 40W	2 x 40W	240W	N/A	No impact, see below.	N/A
	Lamp item description shoulder lamps	Spectra UV-LED	Spectra UV-LED	Spectra UV-LED	Spectra UV-LED	Ergoline Ultra 250W	N/A	Similar, the irradiance characteristics are still comparable as provided under section 18. In terms of functionality and safety there is no impact due to this difference.	N/A
	Filter shoulder lamps	N/A	N/A	N/A	N/A	Ultra Performance 912	N/A	No filters necessary due to no use of high pressure lamps.	N/A

Parameter	Proposed device	Proposed device	Proposed device	Proposed device	Predicate device	Technically referenced device	Evaluation to predicate device	Evaluation to Technically referenced device
Max exposure time [min]	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	N/A	Identical	N/A
Electrical Requirements	230V 3Ø or 230V 2Ø	230V 3Ø or 230V 2Ø	230V 3Ø or 230V 2Ø	230V 3Ø or 230V 2Ø	230V 3Ø or 230V 2Ø	N/A	Identical	N/A
Total power consumption [watts]	14,600 W (w TT) 12,200 W (w/o TT)	14,600 W (w TT) 12,200 W (w/o TT)	11,400 W (w TT)	10,200 W (with AC) 9,000 W (w/o AC)	17,600W	N/A	Similar, the total power consumption is less with the proposed device due to the use of LED technology for facials and less lamps. The irradiance characteristics are still comparable as provided under section 18.	N/A

Parameter	Proposed device	Proposed device	Proposed device	Proposed device	Predicate device	Technically referenced device	Evaluation to predicate device	Evaluation to Technically referenced device
Rated overcurrent protection device (circuit breaker)	60A / 3-pole or 90 A /2-pole (with TT) or 50A / 3-pole or 80 A/2-pole (w/o TT)	60A / 3-pole or 90A /2-pole (with TT) or 50A / 3-pole or 80A /2-pole (w/o TT)	40A /3-pole or 70A / 2-pole (with TT)	40A /3-pole or 70 A/2-pole (with AC) or 40A / 3-pole or 60 A/ 2-pole (w/o AC)	70A / 3-pole 3Ø or 100A / 2-pole 2Ø	N/A	Similar, die overcurrent protection is less with the proposed device due to the use of LED technology for facials and less lamps. The irradiance characteristics are still comparable as provided under section 18.	N/A
Number of wires	4 3Ø or 3 2Ø	4 3Ø or 3 2Ø	4 3Ø or 3 2Ø	4 3Ø or 3 2Ø	4 3Ø or 3 2Ø	N/A	Identical	N/A
Irradiance ratio in accordance with 1040.20	fulfilled	fulfilled	fulfilled	fulfilled	fulfilled	N/A	Identical (refer to section 18 for bench test reports)	N/A
Electrical safety	IEC 60601-1	IEC 60601-1	IEC 60601-1	IEC 60601-1	IEC 60601-1	N/A	Identical	N/A
Electromagnetic compatibility	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	N/A	Identical	N/A

#### 1.4.4 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.

#### 1.4.5 Conclusion:

JK-Holding GmbH believes that the JK 164 / 50-4 Total Light Technology and JK 164 / 50-4 Hybrid Light Technology are substantially equivalent to currently legally marketed devices. Also, all special controls are fulfilled. These devices do not introduce new indications for use, has the same technological characteristics and does not introduce new potential hazards or safety risks.

### 1.5 Device trade names of bundle 4:

Planet Fitness 50/4 PLT III by Ergoline

Ergoline Vitality Pure Light 3

Planet Fitness 50/4 PLT by Ergoline

Ergoline Vitality Pure Light

Common name: Sunlamp product

The following table presents the different variants of the JK 164 / 50-4 Pure Light Technology sunlamp product.

All variants use the same basic device technology and differ only private labelling, exterior design, decor lighting and comfort features.

Model-No.	Variant Name
JK 164 / 50-4 PLT-3 AC	Planet Fitness 50/4 PLT III by Ergoline
JK 164 / 50-4 PLT-3	Ergoline Vitality Pure Light 3
JK 164 / 50-4 PLT AC	Planet Fitness 50/4 PLT by Ergoline
JK 164 / 50-4 PLT	Ergoline Vitality Pure Light

### **1.5.1 Device description:**

#### **Pure Light Technology**

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

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.

### **1.5.2 Legally marketed predicate device 4:**

Device Name:	Affinity 900 AP TT AM/A USA
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

### 1.5.3 Comparison bundle 4 to predicate device:

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

Parameter		Proposed device	Proposed device	Predicate device	Evaluation to predicate device
Model-No.		JK 164 / 50-4 PLT-3 AC JK 164 / 50-4 PLT-3	JK 164 / 50-4 PLT AC JK 164 / 50-4 PLT	JK 155 / 50-4 TT	N/A
Intended 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 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 aesthetic tanning of the human skin, for one person at a time, at the age of 18 or above	Identical
Number of body lamps		50 UV lamps	50 UV lamps	50 UV lamps	Identical
Watts of body lamps		200W	160W	160 W	Similar, the irradiance characteristics are still comparable as provided under section 18. In terms of functionality and safety there is no impact due to this difference.
Lamp item description		GENESIS PLT Pure Light Technology 200W	GENESIS PLT Pure Light Technology 160W	GENESIS VHP12 160W	Different description, no impact, see above.
UV-Facials	Number of UV-facials	4 x 42 UVA-LED	4 x 42 UVA-LED	4 high pressure lamps	Similar, the irradiance characteristics are still comparable as provided under section 18. In terms of functionality and safety there is no impact due to this difference.
	Watts facial lamp	4 x 80W	4 x 80W	4 x 520 W	No impact, see below.



Parameter		Proposed device	Proposed device	Predicate device	Evaluation to predicate device
UV-Facials	Facial item description	Spectra UV-LED	Spectra UV-LED	High pressure lamp Ergoline Ultra 520W	Similar, the irradiance characteristics are still comparable as provided under section 18. In terms of functionality and safety there is no impact due to this difference.
	Filter facial lamps	N/A	N/A	Ultra Performance 412H	No filters necessary due to no use of high pressure lamps.
	Number of low pressure facial lamps	4 x PLT	4 x PLT	3 x Type U	Similar, the irradiance characteristics are still comparable as provided under section 18. In terms of functionality and safety there is no impact due to this difference.
	Watts low pressure facial lamp	8W	8W	8 W	Identical
	Low pressure facial lamps item description	GENESIS PLT Pure Light Technology 8W	GENESIS PLT Pure Light Technology 8W	GENESIS VHP12 8W	Different description, no impact, see above.
Shoulder Tanner	Number of Shoulder lamps	2 x 20 UVA-LED	2 x 20 UVA-LED	7 low pressure lamps	Similar, the irradiance characteristics are still comparable as provided under section 18. In terms of functionality and safety there is no impact due to this difference.
	Watts of shoulder lamps	2 x 40W	2 x 40W	7 x 25W	No impact, see below.

Parameter		Proposed device	Proposed device	Predicate device	Evaluation to predicate device
Shoulder Tanner	Lamp item description shoulder lamps	Spectra UV-LED	Spectra UV-LED	GENESIS VHP12 25 W	Similar, the irradiance characteristics are still comparable as provided under section 18. In terms of functionality and safety there is no impact due to this difference.
	Filter shoulder lamps	N/A	N/A	N/A	No filters necessary due to no use of high pressure lamps.
Max exposure time [min]		12 minutes	12 minutes	12 minutes	Identical
Electrical Requirements		230V 3Ø or 230V 2Ø	230V 3Ø or 230V 2Ø	230V 3Ø or 230V 2Ø	Identical
Total power consumption [watts]		13,400 W (w AC) 12,200 W (w/o AC)	10,600 W (w AC) 9,400 W (w/o AC)	17,000W	Similar, the total power consumption is less with the proposed device due to the use of LED technology for facials. The irradiance characteristics are still comparable as provided under section 18.
Rated overcurrent protection device (circuit breaker)		50A / 3-pole or 90 A /2-pole (with AC) or 50A / 3-pole or 80 A /2-pole (w/o AC)	40A / 3-pole or 70 A /2-pole (with AC) or 40A / 3-pole or 60A /2-pole (w/o AC)	60A / 3-pole 3Ø or 110A / 2-pole 2Ø	Similar, die overcurrent protection is less with the proposed device due to the use of LED technology for facials. The irradiance characteristics are still comparable as provided under section 18.
Number of wires		4 3Ø or 3 2Ø	4 3Ø or 3 2Ø	4 3Ø or 3 2Ø	Identical
Irradiance ratio in accordance with 1040.20		fulfilled	fulfilled	fulfilled	Identical (refer to section 18 for bench test reports)
Electrical safety		IEC 60601-1	IEC 60601-1	IEC 60601-1	Identical
Electromagnetic compatibility		IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	Identical

#### 1.5.4 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.

#### 1.5.5 Conclusion:

JK-Holding GmbH believes that the JK 164 / 50-4 Pure Light Technology are substantially equivalent to currently legally marketed devices. Also, all special controls are fulfilled. These devices do not introduce new indications for use, has the same technological characteristics and does not introduce new potential hazards or safety risks.

#### 1.6 Device trade names of bundle 5:

Planet Fitness 46/3 PLT by Ergoline

Ergoline Vitality Pure Light

Planet Fitness 46/3 HLT by Ergoline

Ergoline Vitality Hybrid Light

Common name: Sunlamp product

The following table presents the different variants of the JK 164 / 46-3 Pure Light Technology and JK 164 / 46-3 Hybrid Light Technology sunlamp product.

All variants use the same basic device technology and differ only private labelling, exterior design, decor lighting, combination of light spectra and comfort features.

Model-No.	Variant Name
JK 164 / 46-3 PLT AC JK 164 / 46-3 PLT	Planet Fitness 46/3 PLT by Ergoline
	Ergoline Vitality Pure Light
JK 164 / 46-3 HLT AC JK 164 / 46-3 HLT	Planet Fitness 46/3 HLT by Ergoline
	Ergoline Vitality Hybrid Light

### **1.6.1 Device Description:**

#### **Pure Light Technology**

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

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.

#### **Hybrid Light Technology**

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.

### **1.6.2 Legally marketed predicate device 5:**

Device Name:	Affinity 700 PF AP AC USA
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

### 1.6.3 Comparison bundle 5 to predicate device:

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

Parameter	Proposed device	Proposed device	Predicate device	Technically referenced device	Evaluation to predicate device	Evaluation to Technically referenced device
Model-No.	JK 164 / 46-3 PLT AC JK 164 / 46-3 PLT	JK 164 / 46-3 HLT AC JK 164 / 46-3 HLT	JK 155 / 46-3	JK 158 / 48-0 HT	N/A	N/A
Intended 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 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 aesthetic tanning of the human skin, for one person at a time, at the age of 18 or above	N/A	Identical	N/A
Number of body lamps	46 UV lamps	46 UV lamps	46 UV lamps	N/A	Identical	N/A
Watts of body lamps	160W	160W	160W	N/A	Identical	N/A
Lamp item description	GENESIS PLT Pure Light Technology 160W	GENESIS PLT Pure Light Technology 160W	GENESIS VHP12 160W	N/A	Different description, no impact, see above.	

Parameter		Proposed device	Proposed device	Predicate device	Technically referenced device	Evaluation to predicate device	Evaluation to Technically referenced device
Number of Total Light-LED		N/A	72 Red LED	N/A	60 Red LED	N/A	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 of Total Light-LED		N/A	95W	N/A	45W	N/A	No impact, see below.
UV-Facials	Number of UV-facials	3 x 42 UVA-LED	3 x 42 UVA-LED	3 high pressure lamps	N/A	Similar, the irradiance characteristics are still comparable as provided under section 18. In terms of functionality and safety there is no impact due to this difference.	N/A
	Watts facial lamp	3 x 80W	3 x 80W	3 x 500W	N/A	No impact, see below.	N/A

Parameter		Proposed device	Proposed device	Predicate device	Technically referenced device	Evaluation to predicate device	Evaluation to Technically referenced device
UV-Facials	Facial item description	Spectra UV-LED	Spectra UV-LED	High pressure lamp Ergoline Ultra 520W	N/A	Similar, the irradiance characteristics are still comparable as provided under section 18. In terms of functionality and safety there is no impact due to this difference.	N/A
	Filter facial lamps	N/A	N/A	Ultra Performance 412 H	N/A	No filters necessary due to no use of high pressure lamps.	N/A
	Number of low pressure facial lamps	2x PLT	2x HLT	2 x Type U	N/A	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.	N/A
	Watts low pressure facial lamp	8W	8W	8W	N/A	Identical	N/A
	Low pressure facial lamps item description	GENESIS PLT Pure Light Technology 8W	GENESIS HLT Hybrid Light Technology 8W	GENESIS VHP12 8W	N/A	Different description, no impact, see above.	

Parameter		Proposed device	Proposed device	Predicate device	Technically referenced device	Evaluation to predicate device	Evaluation to Technically referenced device
Shoulder Tanner	Number of Shoulder lamps	2 x 20 UVA-LED	2 x 20 UVA-LED	7 low pressure lamps	N/A	Similar, the irradiance characteristics are still comparable as provided under section 18. In terms of functionality and safety there is no impact due to this difference.	
	Watts of shoulder lamps	2 x 40W	2 x 40W	7 x 25W	N/A	No impact, see below.	N/A
	Lamp item description shoulder lamps	Spectra UV-LED	Spectra UV-LED	GENESIS VHP12 25 W	N/A	Similar, the irradiance characteristics are still comparable as provided under section 18. In terms of functionality and safety there is no impact due to this difference.	N/A
	Filter shoulder lamps	N/A	N/A	N/A	N/A	No filters necessary due to no use of high pressure lamps.	N/A
Max exposure time [min]	12 minutes	12 minutes	<b>12 minutes</b>	N/A	Identical	N/A	
Electrical Requirements	230V 3Ø or 230V 2Ø	230V 3Ø or 230V 2Ø	230V 3Ø or 230V 2Ø	N/A	Identical	N/A	



Parameter	Proposed device	Proposed device	Predicate device	Technically referenced device	Evaluation to predicate device	Evaluation to Technically referenced device
Total power consumption [watts]	9,600 W (with AC) 8,400 W (w/o AC)	9,600 W (with AC) 8,400 W (w/o AC)	13,700W	N/A	Similar, the total power consumption is less with the proposed device due to the use of LED technology for facials. The irradiance characteristics are still comparable as provided under section 18.	N/A
Rated overcurrent protection device (circuit breaker)	40A / 3-pole or 60A / 2-pole (with AC) or 35A /3-pole or 60A / 2-pole (w/o AC)	40A / 3-pole or 60A / 2-pole (with AC) or 35A /3-pole or 60A / 2-pole (w/o AC)	50A / 3-pole 3Ø or 80A / 2-pole 2Ø	N/A	Similar, die overcurrent protection is less with the proposed device due to the use of LED technology for facials. The irradiance characteristics are still comparable as provided under section 18.	N/A
Number of wires	4 3Ø or 3 2Ø	4 3Ø or 3 2Ø	4 3Ø or 3 2Ø	N/A	Identical	N/A
Irradiance ratio in accordance with 1040.20	fulfilled	fulfilled	fulfilled	N/A	Identical (refer to section 18 for bench test reports)	N/A
Electrical safety	IEC 60601-1	IEC 60601-1	IEC 60601-1	N/A	Identical	N/A
Electromagnetic compatibility	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	N/A	Identical	N/A

**1.6.4 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.

**1.6.5 Conclusion:**

JK-Holding GmbH believes that the JK 164 / 46-3 Pure Light Technology and JK 164 / 46-3 Hybrid Light Technology are substantially equivalent to currently legally marketed devices. Also, all special controls are fulfilled. These devices do not introduce new indications for use, has the same technological characteristics and does not introduce new potential hazards or safety risks.