October 28, 2019

KBL GmbH
Ralf de Andreis
Director Operations
Ringstrasse 24-26
Dernbach, 56307 De

Re: K191881
Trade/Device Name: KBL 7000 alpha hybridSun, KBL 7900 alpha hybridSun, KBL 8000 alpha hybridSun
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: September 24, 2019
Received: September 26, 2019

Dear Ralf de Andreis:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

FOR (Neil Ogden) Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Office of Surgical & 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name

KBL Sunlamp Hybrid Products (KBL 7000 alpha hybridSun, KBL 7900 alpha hybridSun, KBL 8000 alpha hybridSun)

Indications for Use *(Describe)*

KBL Sunlamp Hybrid Products are over-the-counter tanning devices emitting ultraviolet light in the UVB and UVA region of the spectrum intended for tanning of the human skin of an adult person.

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

(according to 21 CFR 807.92)

1. GENERAL INFORMATION

Submitter:	KBL GmbH Ringstrasse 24-26, 56307 Dernbach, GERMANY Phone: +49 (0) 2689 9426-0 Fax: +49 (0) 2689 9426-66 Establishment registration no. 3006116732
Official Correspondent:	Ralf de Andreis Ringstrasse 24-26, 56307 Dernbach, GERMANY Phone: +49 (0) 2689 9426-850 Fax: +49 (0) 2689 9426-500 E-Mail: randreis@kbl.de
Designated U.S. Agent (Contact):	Shepard Bentley Bentley Biomedical Consulting LLC 28241 Crown Valley Parkway, Suite 510(k) Laguna Niguel, CA 92677, USA Phone: +1 949 374 9187 E-Mail: sbentley@bentleybiomed.com
Preparation date:	June 27, 2019

2. PROPOSED DEVICE(S)

Device Name	KBL Sunlamp Hybrid Products
Device Trade Name(s)	KBL 7000 alpha hybridSun KBL 7900 alpha hybridSun KBL 8000 alpha hybridSun
Device common name	Tanning device
Device Classification Name	Booth, Sun Tan
Product Code	LEJ (21CFR 878.4635)
Classification Panel	General & Plastic Surgery
Device Class	Class II - Special Controls

3. PREDICATE DEVICE(S)

Device Name	KBL Sunlamp Products
Device Trade Name(s)	KBL 7900 alpha KBL 6800 alpha
Device common name	Tanning device
Device Classification Name	Booth, Sun Tan
Product Code	LEJ (21CFR 878.4635)
Classification Panel	General & Plastic Surgery
Device Class	Class II - Special Controls
510(k) No.	K151962

4. DEVICE DESCRIPTION

KBL Sunlamp Hybrid Products are whole-body tanning devices basically consisting of a mechanical structure equipped with artificial light sources using the hybrid light technology. The hybrid light technology produces ultraviolet radiation and radiation in the visual range of the light spectrum.

The UV light is intended for irradiation of any part of the living human body to induce skin tanning. The user is lying on a bench.

5. INDICATIONS FOR USE

The Indications for use for the Proposed Devices are identical to the Predicate Devices as shown in Table 1 below:

Table 1

Proposed Device	Predicate Device
KBL Sunlamp Hybrid Products are over-the-counter tanning devices emitting ultraviolet light in the UVA and UVB region of the spectrum intended for tanning of the human skin of an adult person.	KBL Sunlamp Products are over-the-counter tanning devices emitting ultraviolet light in the UVA and UVB region of the spectrum intended for tanning of the human skin of an adult person.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

We believe that the Technological Characteristics of the Proposed Devices in comparison to the Predicate Devices show that they are substantially equivalent. See table 2, 3 and 4 below:

Table 2	**PROPOSED DEVICE** KBL Sunlamp Hybrid Product	**PREDICATE DEVICE** KBL Sunlamp Product	**EVALUATION**
Device Trade Name	**KBL 7000 alpha hybridSun**	KBL 6800 alpha	N/A
Number of Lamps Canopy	18x pureSunlight lamps / 8x smartSunlight (uv+red light) lamps	20x megaLine lamps / 6x megaLine lamps /	Equivalent The irradiance characteristics are still equivalent to the predicate device as provided under Performance Testing table (radiometric measurement results). The safety was confirmed by appropriate tests according to IEC 62471. In terms of funtionality and safety there is no impact due to this difference.
Watt	160	160 / 80	
Number of Lamps Bench	14x pureSunlight lamps / 6x smartSunlight (uv+red light) lamps	20x megaLine lamps	Equivalent The irradiance characteristics are still equivalent to the predicate device as provided under Performance Testing table (radiometric measurement results). The safety was confirmed by appropriate tests according to IEC 62471. In terms of functionality and safety there is no impact due to this difference.
Watt	180	180	
Number of Facial Lamps	4x megaLine HP 800	4x megaLine HP 800	Identical
Watt	600	600	Identical
Number of Shoulder Lamps	2x ms 250	2x ms 250	Identical
Watt	250	250	Identical
Number of LEDs (vis red light)	40x beautyBooster	40x Enhanced LED Illumination	Identical
Watt	1	1	Identical
Max. Exposure Time in min.	10	10	Identical
Dimensions in Inches (height x width x depth)	when closed ~60,59"x ~93,86"x ~56,34" when open ~80,24"x ~93,86"x ~56,34"	when closed: ~60,39"x ~93,86"x ~56,34" when open: ~76,46"x ~93,86"x ~56,34"	Equivalent The dimensions are equivalent to the predicate device. In terms of functionality and safety there is no impact due to this difference.

Table 3	**PROPOSED DEVICE** KBL Sunlamp Hybrid Product	**PREDICATE DEVICE** KBL Sunlamp Product	**EVALUATION**
Device Tade name	**KBL 7900 alpha hybridSun**	KBL 7900 alpha	N/A
Number of Lamps Canopy	18x pureSunlight lamps / 8x smartSunlight (uv+red light) lamps	20x megaLine lamps / 6x megaLine lamps /	Equivalent The irradiance characteristics are still equivalent to the predicate device as provided under Performance Testing table (radiometric measurement results). The safety was confirmed by appropriate tests according to IEC 62471. In terms of functionality and safety there is no impact due to this difference.
Watt	160	160 / 80	
Number of Lamps Bench	16x pureSunlight lamps / 8x smartSunlight (uv+red light) lamps	24x megaLine lamps	Equivalent The irradiance characteristics are still equivalent to the predicate device as provided under Performance Testing table (radiometric measurement results). The safety was confirmed by appropriate tests according to IEC 62471. In terms of functionality and safety there is no impact due to this difference.
Watt	180	180	
Number of Facial Lamps	4x megaLine HP 800	4x megaLine HP 800	Identical
Watt	600	600	Identical
Number of LEDs (vis red light)	40x beautyBooster	40x Enhanced LED Illumination	Identical
Watt	1	1	Identical
Number of Shoulder Lamps	2x ms 250	2x ms 250	Identical
Watt	250	250	Identical
Max. Exposure Time in min.	10	10	Identical
Dimensions in Inches (height x width x depth)	when closed ~67,44"x ~93,86"x ~56,34" when open ~82,16"x ~93,86"x ~56,34"	when closed ~67,44"x ~93,86"x ~56,34" when open ~82,16"x ~93,86"x ~56,34"	Identical

Table 4	**PROPOSED DEVICE** KBL Sunlamp Hybrid Product	**PREDICATE DEVICE** KBL Sunlamp Product	**EVALUATION**
Device Trade name	**KBL 8000 alpha hybridSun**	KBL 7900 alpha	N/A
Number of Lamps Canopy	18x pureSunlight lamps / 8x smartSunlight (uv+red light) lamps	20x megaLine lamps / 6x megaLine lamps /	Equivalent The irradiance characteristics are still equivalent to the predicate device as provided under Performance Testing table (radiometric measurement results). The safety was confirmed by appropriate tests according to IEC 62471. In terms of functionality and safety there is no impact due to this difference.
Watt	160	160 / 80	
Number of Lamps Bench	16x pureSunlight lamps / 8x smartSunlight (uv+red light) lamps	24x megaLine lamps	Equivalent The irradiance characteristics are still equivalent to the predicate device as provided under Performance Testing table (radiometric measurement results). The safety was confirmed by appropriate tests according to IEC 62471. In terms of functionality and safety there is no impact due to this difference.
Watt	180	180	
Number of Facial Lamps	4x megaLine HP 800	4x megaLine HP 800	Identical
Watt	600	600	Identical
Number of Shoulder Lamps	2x ms 250	2x ms 250	Identical
Watt	250	250	Identical
Number of LEDs (vis red light)	70x beautyBooster	40x Enhanced LED Illumination	Equivalent The irradiance characteristics are still equivalent to the predicate device as provided under Performance Testing table (radiometric measurement results). The safety was confirmed by appropriate tests according to IEC 62471. In terms of functionality and safety there is no impact due to this difference.
Watt	1	1	Identical
Max. Exposure Time in min.	10	10	Identical
Dimensions in Inches (height x width x depth)	when closed: ~67,44“x ~93,86“x ~56,34“ when open ~82,16“x ~93,86“x ~56,34“	when closed~67,44“x ~93,86“x ~56,34“ when open: ~82,16“x ~93,86“x ~56,34“	Identical

7. PERFORMANCE DATA

The following non-clinical performance tests were performed for all proposed KBL sunlamp products:

- Biocompatibility testing in accordance with DIN EN ISO 10993-1:2010-04; DIN EN ISO 10993-5:2009-10; DIN EN ISO 10993-12:2012-10;
- Electrical and mechanical safety testing according to IEC 60601-1:2005 + Corr.:2006 + Corr.:2007 + A1:2012 (IEC 60335-1:2012, and UL482:2005/09/02 Ed.9 Rev. 2013/10/03)
- Electromagnetic compatibility testing in compliance with IEC 60601-1-2:2014.
- Spectral emission measurement based on the test procedure for measuring the spectral emission in accordance to IEC 60335-2-27:2013.
- Software verification and validation testing according to FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".
- Performance Standards testing in accordance with 21 CFR 1040.20
- Irradiance ratio limits are in accordance with 21 CFR 1040.20(c)(1).
- Maximum timer intervals and exposure schedules have been determined according to FDA's "Policy on maximum timer interval and exposure schedule for sunlamp products".

8. CONCLUSION

Based on an analysis of the technological characteristics, non-clinical performance data and indications for use, KBL GmbH believes that the Proposed Devices are substantially equivalent to the legally marketed Predicate Devices and do not raise any new issues of safety and effectiveness.

End of 510(k) Summary