DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 15, 2016

KBL AG
Mr. Norbert Becker
Head of Technical Department
Ringstrasse 24-26
Dernbach, Rheinland-Pfalz, Germany 56307

Re: K151962
Trade/Device Name: KBL Sunlamp Products
Regulation Number: 21 CFR 878.4635
Regulation Name: Ultraviolet lamp for tanning
Regulatory Class: Class II
Product Code: LEJ
Dated: September 12, 2016
Received: September 14, 2016

Dear Mr. Becker:

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. 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 Part 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Christopher J. Ronk -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151962

Device Name

KBL Sunlamp Products

Indications for Use *(Describe)*

KBL Sunlamp 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K151962

510(k) SUMMARY

(according to 21 CFR 807.92)

1. GENERAL INFORMATION

Submitter: KBL AG
Ringstrasse 24-26
56307 Dernbach, GERMANY
Phone: +49 (0) 2689 9426-0
Fax: +49 (0) 2689 9426-66

Contact person: Norbert Becker
Ringstrasse 24-26
56307 Dernbach, GERMANY
Phone: +49 (0) 2689 9426-525
Fax: +49 (0) 2689 9426-500
E-mail: nbecker@kbl.de

Preparation date: June 8, 2015

2. PROPOSED DEVICE(S)

Device Bundling Name: KBL Sunlamp Product

Trade Name(s): KBL 6800 alpha / KBL 7900 alpha
KBL 4800 alpha / KBL 5600 alpha
KBL Tower Space 2000 / KBL Tower Space 3000
KBL Tower pure Energy 5.0

Common Name: Tanning device

Classification Name: Sunlamp product (21 CFR 878.4635, Product Code LEJ)

All Proposed Devices have originally been listed as Class I devices (510(k)-exempt sunlamp products) and legally offered for sale before September 2, 2014. In accordance with the Final Order (Federal Register, Volume 79, Number 5) the proposed devices are used as Predicate Devices for Substantial Equivalence purposes.

3. PREDICATE DEVICE(S)

Trade Name(s):	KBL 6800 alpha / KBL 7900 alpha KBL 4800 alpha / KBL 5600 alpha KBL Tower Space 2000 / KBL Tower Space 3000 KBL Tower pure Energy 5.0
Common Name	Tanning device
Classification Name:	Sunlamp product (21 CFR 878.4635, Product Code LEJ)

4. DEVICE DESCRIPTION

KBL Sunlamp Products are whole-body tanning devices basically consisting of a mechanical structure equipped with artificial light sources producing ultraviolet light in the UVA and UVB region of the light spectrum.
The UV light is intended for irradiation of any part of the living human body to induce skin tanning. The UVA light primarily generates a superficial tan which appears rapidly and is intensive but also fades more rapidly whereas the UVB light generates more long term tanning results.
The user is either standing in the middle of the KBL Sunlamp Product if it is a vertical device (tanning tower) or lying on a bench if it is a horizontal device (tanning bed).

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 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 (Table 2).

Table 2

Brand and type name ↓	Number of Lamps Canopy	Watts	Number of Lamps Bench	Watts	Number of Facial Lamps	Watts	Number of Shoulder Lamps	Watts	Max. Exposure time in min	Dimentions in inches (height x width x depth)
Proposed Device KBL 6800 alpha	26 / 0 or 20 / 6 or 24 / 2	160 / 80	20	180	4	600	2	250	10	when closed: ~60,39“ x ~93,70“ x ~56,30“ when open: ~76,46“ x ~93,70“ x ~56,30“
Predicate Device KBL 6800 alpha	26 / 0 or 20 / 6 or 24 / 2	160 / 80	20	180	4	600	2	250	10	when closed: ~60,39“ x ~93,70“ x ~56,30“ when open: ~76,46“ x ~93,70“ x ~56,30“
Proposed Device KBL 7900 alpha	20 / 6	160 / 80	24	180	4	600	2	250	10	when closed: ~67,44“ x ~93,70“ x ~56,30“ when open: ~82,16“ x ~93,70“ x ~56,30“
Predicate Device KBL 7900 alpha	20 / 6	160 / 80	24	180	4	600	2	250	10	when closed: ~67,44“ x ~93,70“ x ~56,30“ when open: ~82,16“ x ~93,70“ x ~56,30“
Proposed Device KBL 4800 alpha	22 / 2	160 / 80	16	180	3	500	N/A	N/A	12	when closed: ~53,94 x ~91,74 x ~62,21 when open: ~67,33 x ~91,74 x ~56,70
Predicate Device KBL 4800 alpha	22 / 2	160 / 80	16	180	3	500	N/A	N/A	12	when closed: ~53,94 x ~91,74 x ~62,21 when open: ~67,33 x ~91,74 x ~56,70
Proposed Device KBL 5600 alpha	24 / 2	160 / 80	16	180	4	500	N/A	N/A	12	when closed: ~58,27 x ~91,74 x ~63,39 when open: ~70,87 x ~91,74 x ~56,70
Predicate Device KBL 5600 alpha	24 / 2	160 / 80	16	180	4	500	N/A	N/A	12	when closed: ~58,27 x ~91,74 x ~63,39 when open: ~70,87 x ~91,74 x ~56,70
Proposed Device KBL Tower space 2000	50	180	N/A	N/A	N/A	N/A	N/A	N/A	11	when closed: 85.83 x 55.12 x 55.31 when open: 85.83 x 55.12 x 77.28
Pedicate Device KBL Tower space 2000	50	180	N/A	N/A	N/A	N/A	N/A	N/A	11	when closed: 85.83 x 55.12 x 55.31 when open: 85.83 x 55.12 x 77.28

Proposed Device KBL Tower space 3000	52	180	N/A	N/A	N/A	N/A	N/A	N/A	11	when closed: 85.83 x 55.12 x 58.98 when open: 85.83 x 55.12 x 77.09
Predicate Device KBL Tower space 3000	52	180	N/A	N/A	N/A	N/A	N/A	N/A	11	when closed: 85.83 x 55.12 x 58.98 when open: 85.83 x 55.12 x 77.09
Proposed Device KBL Tower pureEnergy 5.0	52	200	N/A	N/A	N/A	N/A	N/A	N/A	10	when closed: 93,23 x 54,93 x 48,55 when open: 93,23 x 54,93 x 72,56
Predicate Device KBL Tower pureEnergy 5.0	52	200	N/A	N/A	N/A	N/A	N/A	N/A	10	when closed: 93,23 x 54,93 x 48,55 when open: 93,23 x 54,93 x 72,56

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 Ed 3.1 2012/08 (IEC 60335-1:2010, 5th ed. and UL482:2005/09/02 Ed.9 Rev. 2013/10/03)
- Electromagnetic compatibility testing in compliance with IEC 60601-1-2:2007, modified.
- Spectral emission measurement based on the test procedure for measuring the spectral emission in accordance to IEC 60335-2-27:2009, 5th ed.
- 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 AG 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