DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 22, 2018

KDB Inc., d.b.a. Sperti Sunlamp
Susan Anthoney
FDA Consultant / Document Specialist
2424 Dempster Dr.
Coralville, Iowa 52241

Re: K151721
Trade/Device Name: Fiji Sun Fluorescent Tanning Unit
Regulation Number: 21 CFR 878.4635
Regulation Name: Ultraviolet Lamp For Tanning
Regulatory Class: Class II
Product Code: LEJ
Dated: June 25, 2015
Received: June 25, 2015

Dear Susan Anthoney:

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 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 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" (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 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,

Jennifer R. Stevenson -S3

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)*
K151721

Device Name
Fiji Sun Fluorescent Tanning Unit (FIJI Sun)

Indications for Use *(Describe)*
The Fiji Sun Fluorescent Tanning Unit device (FIJI Sun) is intended to provide ultraviolet light for the purpose of stimulating a tanning response in the skin.

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)

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)*

510(k) Summary

(807.92)

K151721

Submission Date: March 18, 2018

1. Submitter Information:

AEGIS Regulatory, Inc. – Susan Anthoney-DeWet
2424 Dempster Drive
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For Manufacturer:

KBD, Inc. d/b/a Sperti Sunlamp
Attn: James Shepard
2550 American Ct.
Crescent Springs, KY. 41017

2. General Information:

2.1 Regulation Description: Ultraviolet lamp for tanning

2.2 Common/Usual Name: Booth, Suntan

2.3 Proprietary Names: FijiSun Fluorescent Tanning Unit (FIJI Sun)

2.4 Classification: Class II

2.5 Classification Number: 878.4635

2.6 Product Code: LEJ

3. Device Description:

The FIJI Sun Fluorescent Tanning Unit (FIJI SUN) is a small tabletop sunlamp product which uses four Sperti brand ultraviolet lamps (model number: FRT20TI21BUHO) manufactured for KBD. The FIJI Sun Fluorescent Tanning Unit uses a mechanical timer with a maximum timer interval of 15 minutes and a minimum timer interval of one minute. The maximum timer interval error as a percent of that interval is +/- 6%. Output performance testing and FDA performance standards were used to determine the maximum timer interval and the recommended exposure schedule which is on the device labeling and in the user instructions. Two pair of protective eye wear are supplied with the device. The spectral transmittance to the eye of the protective eyewear is 0.0008 in the wavelength range from 200 nm to 320 nm and 0.0004 in the wavelength range from 320nm to 400 nm and is sufficient over the wavelengths greater that 400nm to

enable the user to see clearly enough to reset the timer. In order for the product to fulfill its function it emits UV light In the wavelength range from 290 nm to 400 nm and the emission level is one SED (100 *J/m^2).* The minimum use distance specified in the product labeling and the user instruction is 18 inches. Adequate directions for use, warnings and contraindications are included in user instructions provided with the device and in the device labeling. There is no software contained in the device. The device is sold as Over the Counter (OTC).

4. Intended/Indications for Use:

The Fiji Sun Fluorescent Tanning Unit device (FIJI Sun) is intended to provide ultraviolet light for the purpose of stimulating a tanning response in the skin.

5. Predicate Device:

The proposed device is substantially equivalent to the following predicate device:

1. Predicate Device: FijiSun Fluorescent Tanning Unit (KBD, Inc.)

K Number (NONE)- ***CDRH Accession Number 1120263-000**,

*The device included in this submission existed and was legally marketed prior to September 2, 2014. FDA accession numbers are included in this submission. Federal Register Volume 79, Number 105 (Monday, June 2, 2014)] "Any sunlamp product or UV lamp intended for use in a sunlamp product legally marketed on or before September 2, 2014 ….can be used as a predicate device in a 510(k)".

6. Substantial Equivalence to Predicate Device:

The predicate device is identical to the proposed FijiSun Fluorescent Tanning Unit device and no significant differences exist between the devices.

After an analysis of the safety, indications, intended uses, performance features, design materials, chemical composition, energy source, power output, technological properties, treatment areas, treatment regimes and methods of operation, the manufacturer believes that no significant differences exist between the proposed device and the predicate device listed in section 5 of this summary.

7. Performance Standards:

The FijiSun Fluorescent Tanning Unit has been tested and is in conformance to the international consensus standard:

ELECTRICAL SAFETY:
Recognition Number 19-4:
IEC/EN 60601-1:2005 Edition 3/(R)2012 And A1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (Iec 60601-1:2005, Mod). (General II (ES/EMC))

This device has also been tested under and is in compliance with performance standards that have been established for such devices under Section 1040.20 of the Federal Food, Drug, and Cosmetics Act.

- Specific performance testing (spectral analysis) was done on these devices to measure irradiance to ensure compliance with radiation limits set out in 21 CFR 1040.20.
- Specific performance testing was done on the included protective eyewear (goggles) to ensure spectral transmittance did not exceed the value limits set out in 21 CFR 1040.20 while enabling the user to see clearly enough to reset the timer.

Conclusion

After an analysis of the safety, indications, intended uses, performance features, design materials, chemical composition, energy source, power output, technological properties, and methods of operation, the manufacturer believes that no significant differences exist between the proposed device and the predicate device listed in section 5 of this summary. Therefore, substantial equivalency is requested.