DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 19, 2016

Medtek Lighting Corp D/b/a Peacock Tanning
% Ms. Susan Anthoney-Dewet
FDA Consultant
Aegis Regulatory, Inc.
2424 Dempster Drive
Coralville, Iowa 52241

Re: K152452
Trade/Device Name: Express Tan Models 1000HT/1600HT/2000CT/2000HT/3200
Regulation Number: 21 CFR 878.4635
Regulation Name: Ultraviolet lamp for tanning
Regulatory Class: Class II
Product Code: LEJ
Dated: April 22, 2016
Received: April 25, 2016

Dear Ms. Anthoney-Dewet:

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 -A

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)*
K152452

Device Name
Peacock Tanning, Express Tan Models 1000HT/1600HT/2000CT/2000HT/3200

Indications for Use *(Describe)*
Medtek Lighting, LLC's Peacock Tanning, Express Tan Models 1000HT, 1600HT, 2000CT, 2000HT, 3200 are intended to provide ultraviolet light to tan the skin, in male and female users, not under the age of 18 years.

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.

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

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"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."

510(k) Summary

K152452

Submission Date: August 18, 2015

1. Submitter Information: AEGIS Regulatory, Inc. – Susan Anthoney-DeWet
2424 Dempster Drive
Coralville, IA 52241
Tel.: 865-982-5552
Email: sue@fdalistingconsultants.com

For Manufacturer: MedTek Lighting, Inc. d/b/a Peacock Tanning
Attn: Mr. Gary Richardson
3 Depot St.
Hudson Falls, NY 12839
Tel.: 518-747-3310

2. General Information:

2.1 Regulation Description: Ultraviolet lamp for tanning

2.2 Common/Usual Name: Booth, Sun Tan

2.3 Proprietary Names: Peacock Tanning, Express Tan models 1000HT/1600HT/2000CT/2000HT/3200

2.4 Classification: Class II

2.5 Classification Number: 878.4635

2.6 Product Code: LEJ

3. Device Description:

The Express Tan 1000HT device is a skin tanning device, wall mounted or used on an accessory stand with a single lighting panel with 10 Cosmedico (T12/F71"/100w) lamps, driven by standard electrical lighting systems at 120 Volts, producing primary UV-A emissions within an enclosed metal (structure) and acrylic (exposure) housing and utilized only with included protective eyewear, as outlined in 21 CFR 1040.20 (c). A digital timer is used to program exposure times.

Cabinet dimensions: 85.5" high, 5" deep, 22" wide – when door panels are closed.
A digital control timer module is used to program exposure times.

The Express Tan models1600HT/2000CT/2000HT/3200 are skin tanning devices, wall mounted with 4 lighting panels containing an array of a total of 16, 20, or 32 Cosmedico

(T12/F71"/100w) lamps, driven by standard electrical lighting systems at 120 Volts, producing UV-A emissions within an enclosed metal (structure) and acrylic (exposure) housing, and that is utilized only with included protective eyewear, as outlined in 21 CFR 1040.20 (c). A digital timer is used to program exposure times.

Cabinet dimensions: 92" high, 8" deep, 50" wide – when panels are closed.

In order to ensure safety of tanning devices used in the home environment (Models 1000HT/1600HT/2000HT), the sponsor provides training to the consumer before the product is shipped out. Records of this training are kept according to the Sponsor's record keeping procedures.

This training procedure includes:
Overview of the User Manual

- Help in determining Skin Type, Effective Exposure schedule based on skin type, what to do in order to avoid over exposure;
- Going over Warnings, Contraindications, Precautions;
- Going over safety features –i.e. emergency shut-off switch;
- Going over list of photosensitizing agents (list in manual);
- Providing a "Tanning Exposure Log" so that a home consumer may keep track of sessions;
- Tanning bed is not to be used by any person under the age of 18 years;

And finally, having the consumer sign a "Risk Acknowledgement Certification" form. A sample of this form can be found in the proposed amendments to 21 CFR 878.4635 (c) (4)Risk acknowledgement certification, *" General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products; Proposed Rule,"* 80 FR 79493 (22 Dec. 2015).

4. Intended Use:

The Express Tan Models 1000HT, 1600HT, 2000CT, 2000HT, 3200 are intended to provide ultraviolet light to tan the skin in male and female users, not under the age of 18 years.

5. Predicate Device:

The proposed devices are substantially equivalent to the following predicate devices, which are currently in safe and effective commerce:

1. Primary Predicate: K Number (NONE)-ACCESSION NUMBER: 8920525, PEACOCK TANNING EXPRESS TAN MODELS 1000/1600/2000/3200 (MEDTEK LIGHTING CORP)
2. K944015 - HARPO SUNBED, SUN TANNING MACHINE (HARPO INDUSTRIES) 1994 clearance, Product Code:LEJ

3. K871237 - SUN CAPSULE I & II SUNTANNING BOOTH (SUN CAPSULE, INC) 1987 clearance, Product Code:FTC

6. Substantial Equivalence to Predicate Device:

The primary predicate devices are identical to the proposed Express Tan devices and no differences exist between the devices.
The secondary predicate devices differ from the proposed Express Tan devices in that the proposed devices have additional safety features and newer components but have have the same intended use as the predicate devices; have the same technological characteristics as the predicate devices and conform to the special controls required by the reclassification order.

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 device and the predicate device listed in section 5 of this summary.

7. Performance Standards:

The **Express Tan Models 1000HT, 1600HT, 2000HT, 2000CT, 3200HT** have been tested and conform to international consensus standards:

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))

EMC:
Recognition Number 19-1:
IEC 60601-1-2 Edition 4: 2014, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests. (General II (ES/EMC))

These devices have also been tested under and are 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 complaince 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, treatment areas, treatment regimes and methods of operation, the manufacturer believes that no significant differences exist between the device and the predicate device listed in section 5 of this summary. Therefore, substantial equivalency is requested.