April 19, 2018

LPI, Inc.
Christopher Steadman
VP Tanning Operations
506 Twin Oaks Drive
Johnson City, Tennessee 37601

Re: K180576
Trade/Device Name: Solar Storm, Solar Wave, Sunco, and ESB (Avalon, Galaxy, Grande, Oasis, Elite and Leisure Select)
Regulation Number: 21 CFR 878.4635
Regulation Name: Ultraviolet Lamp for Tanning
Regulatory Class: Class II
Product Code: LEI
Dated: February 28, 2018
Received: March 5, 2018

Dear Christopher Steadman:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180576

Device Name
Solar Storm/Solar Wave, Sunco, and ESB (Galaxy, Avalon, Leisure Select, Elite,Oasis and Grande)

Indications for Use *(Describe)*
The device is intended to be used for the tanning of human 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)

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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501(k) Summary
As required by 21 CFR 807.92(c)

Date
February 28, 2018

Submitter and Contact Details
LPI, Inc.
506 Twin Oaks Drive
Johnson City, TN 37601
Chris Steadman, VP Tanning Operations
Phone: 423-349-2920
Email: csteadman@lpiinc.com

Device Name
Solar Storm, Solar Wave, Sunco, and ESB (Avalon, Galaxy, Grande, Oasis, Elite and Leisure Select)

Device Name/Classification

Trade Name:	Solar Storm, Solar Wave, Sunco, and ESB (Avalon, Galaxy, Grande, Oasis, Elite and Leisure Select)
Common Name:	Tanning bed/booth
Classification Name:	Ultraviolet lamp for tanning
Device Classification:	Class II, 21 CFR 878.4635
Product Code:	LEJ

Predicate Devices
Per the special controls for these devices and noted in the Federal Register Vol 79, No 105, dated June 2, 2014 (Docket No. FDA-2013-N-0461), LPI, Inc. tanning units listed below serve as their own predicate devices as they were on the market prior to September 2, 2014 and can demonstrate substantial equivalence.

- ESB –14, 16, 18, 24, and Oasis 36(booth)
- Solar Storm 16R, 24S, 24R, 24C, 32S, 32R, 32C, 36ST, 48ST(Booth)
- Solar Wave 16, 24
- Sunco – 16XS, 24XS, 32XS, and 48Vertical (Booth)

Device Description
The series of tanning bed/booths are available in four configurations. Units consist of LPI, Inc. branded and OEM tanning beds and booths.

- ESB –14, 16, 18, 24, and Oasis 36(booth)
- Solar Storm 16R, 24S, 24R, 24C, 32S, 32R, 32C, 36ST, 48ST(Booth)
- Solar Wave 16, 24
- Sunco – 16XS, 24XS, 32XS, and 48Vertical (Booth)

Each configuration consists of a metal structure with lamps placed equally distant horizontally (beds) or vertical (booths) and arranged in manner to provide the tanner an even tan. The user of tanning beds lies down on the bench section and pulls down the canopy cover, which is equipped with a counterweighted gas springs/shocks in order for this section of the bed to open and close. The user of a tanning booth stands within the sections of the booth. The section of the booth (door) also has gas springs/shocks and wheels to close the door. All units have electronic type ballasts that powers the lamps. Each unit is also equipped with a settable electronic timer which is controlled by a time setting of 10, 15, or 20 minutes. Timers are also equipped with an “off” button to allow user to turn off the lamps any time prior to the duration of the set timer.

All tanning units meet the allowable limits of UV irradiation exposure based on limits set by the FDA performance standard 21 CFR 1040.20 and FDA Guidance letter dated August 21, 1986 titled Policy on maximum Timer internal and Exposure Schedule for Sunlamp Products.

Intended Use

The device is intended to be used for the tanning of human skin.

Comparison of Characteristics

The LPI, Inc. Branded and OEM units described above are identical to the units previously marketed as Class K devices.

Testing of UV irradiance was performed to determine a guideline for testing of units during the production. The results of these tests provide reasonable assurance that the device is designed and tested to assure conformance to the requirements for its intended use and performs comparably to the existing device. All LPI, Inc. beds/booths are considered substantially equivalent to the same predicate devices.

The labeling of devices and user manual contraindications and warnings for LPI, Inc Branded and OEM beds/booths are in compliance with the requirements of 21 CFR 1040.20.

Timers on the beds/booths are set for the time intervals of 10, 15, or 20 minutes based on the type of timer in the unit. All timer Units are set for the time interval and tested at 100% prior to installation.

Performance Testing

(Non-Clinical)

UV irradiance testing results performed on all lamp configurations confirm the dosage is within allowable limits set by the FDA performance standard 21 CFR 1040.20 and FDA Guidance letter dated August 21,1986 titled "Policy on Maximum Timer internal and Exposure Schedule for Sunlamp Products.

Usability data is included with the submission.

Biocompatibility Testing

The subject devices are categorized as surface devices which only come into contact with the intact skin for a duration of less than 24 hours. The material that comes into contact with the patient's skin is Poly(Methyl methacrylate/Butyl acrylate) CAS No. 25852-37-3, which has been shown to be biocompatible via ISO 10993 and is identical to the material used in these same devices when previously sold as Class I devices.

Electrical Safety and Electromagnetic Compatibility (EMC)

IEC 60601-1 and 60601-1-2 testing were conducted on denoted devices, which were shown to pass the tests conducted.

No further testing was performed, as devices are identical to the predicate devices.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry, "Guidance for Industry, FDA Reviewers and Compliance on "Off-the-Shelf" Software used in Medical Devices." The software for this device is considered as a "Minor Level of Concern before Mitigations".

User Training

LPI has established a training completion confirmation for each purchaser of residential and commercial tanning beds and booths.

The following topics are covered at a minimum.

1. Use of instruction manual
2. Consult physician regularly for skin cancer when repeatedly exposed to UV radiation
3. Contraindicate for people under 18 Years of age
4. Contraindicate persons must not use if skin lesions or open wounds are present
5. Should not be used on individuals who have had skin cancer or have a family history
6. Repeated exposure and overexposure, allowance time between tanning sessions
7. Use of only approved eyewear during tanning session
8. Discontinue tanning if experiencing health concerns

Conclusion

The predicate devices do not negatively affect a finding of substantial equivalence between the subject devices and are identical technologically, with a few minor aesthetic differences.