DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 14, 2016

PC Marketing, Inc.
c/o Shepard Bentley, RAC
Bentley Biomedical Consulting, LLC
28241 Crown Valley Parkway, Suite 510(k)
Laguna Niguel, CA 92677

Re: K153479
Trade/Device Name: uwe sun tanning beds/booths P90, iBED EVG, iSUN HP, SILVERBULLET SE, LOTUS
Regulation Number: 21 CFR 878.4635
Regulation Name: Ultraviolet lamp for tanning
Regulatory Class: Class II
Product Code: LEJ
Dated: March 13, 2016
Received: March 17, 2016

Dear Mr. Bentley:

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" (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,

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)*
K152364

Device Name
uwe sun tanning beds/booths P90, iBED EVG, iSUN HP, SILVERBULLET SE, LOTUS

Indications for Use *(Describe)*
Intended to provide ultraviolet light to tan 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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Section 5

510(k) Summary

Name and address of submitter:

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Date of submission: 20 August, 2015

Trade name of the device: The bundle of uwe sun tanning beds/booths consists of:

- P90
- iBED EVG
- iSUN HP
- SILVERBULLET SE
- LOTUS

Common name of the device: uwe sun tanning beds/booths (bundled)

Classification reference: 21 CFR 878.4635

Product code: LEJ

Predicate Devices: uwe sun tanning beds/booths

5.1 DEVICE DESCRIPTION

5.2 Intended Use

Intended to provide ultraviolet light to tan the skin.

5.2.1 Device Components

The uwe sun tanning beds/booths consist of several essential parts. These parts differ between the bed and the booth models.

The beds consist of a lying area and a canopy. The booth consists of a cabin and a door. Both sunlamp products contain the same electronic components like the main board and the relay board, fans, lamps etc.

The most significant differences are the decorating design elements and the implemented features like "Body Mist" and "Aroma". These constitute the several looks of the beds and booths.

The primary technical components of a tanning device are an artificial source of UV radiation, a variety of filters and reflectors as well as a mechanical structure with a defined active surface. Different tanning results can be achieved in varying strength tanning devices. This is due to the different strength UV lamps and the different UV-A and UV-B proportions of the UV radiation.

The UV-A proportion primarily generates a superficial tan, which appears rapidly and is intensive but also fades more rapidly, the UV-B radiation is primarily responsible for more long-term tanning results.

The disadvantage of the UV-B radiation is that the tan does not become visible until one or two days after visiting the tanning salon.

Therefore, the appropriate tanning device is to be selected depending on the desired tanning goal.

5.2.2 Comparison to Predicate Devices and Summary of Differences

Prior to September 2, 2014, the basic ultraviolet sunlamps named in this 510(k) existed and were offered for sales as legally marketed Class I 510(k)-exempt medical devices.

For the basis of this 510(k), PC Marketing, Inc. claims substantial equivalence to these legally marketed devices. Since none of the sun tanning booths named in this 510(k) have changed in 1) intended use or 2) technological design characteristics after September 2, 2014, essentially the contemporary sun tanning booths are identical to the predicate devices (i.e., those basic sun tanning booths offered for sale prior to the FDA's cutoff date of Sept. 2, 2014).

Such an approach of using the legally marketed Class I medical devices as predicate devices is validated in the Final Reclassification Order published on June 2, 2014 in the Federal Register Vol. 79, No. 105, Page 31212, whereby it stated that:

"FDA cleared several 510(k)s for sunlamp products prior to exempting the devices from premarket notification submission. At least one 510(k) for a sunlamp product has cleared since then under product code LEJ. These cleared sunlamp products, as well as ***any 510(k)-exempt sunlamp product or UV lamp intended for use in a sunlamp product legally offered for sale on or before September 2, 2014, can serve as predicates for substantial equivalence purposes***."

This 510(k) provides ample evidence that the subject devices all have the same intended uses and substantially equivalent technological characteristics with each other, and conform to the special controls required by the reclassification order.

In short, the sun tanning booths described within this 510(k) submission are as safe and as effective as the predicate devices, as they are unchanged from their Class I configurations.

The devices differ in position, intensity, type and number of lamps. Related to these dimensions the duration until the maximum energy intensity and hence the maximum exposure time is reached, differs. The maximum exposure time factory preset. This set time cannot be exceeded by any other component.
The maximum irradiance of all devices fulfill the requirements of FDA 21 CFR 1040.20.

The devices are equivalent to the predicate devices within the intended uses, which are identical, and the technological characteristics, which are nearly identical.

5.3 Discussion of Non-clinical Tests

The bundled **uwe sun tanning beds/booths** comply with the applicable safety and performance standards and therefore are safe and effective for their intended use. The devices have been thoroughly tested including electrical and thermal safety, electromagnetic compatibility, mechanical and environmental tolerance, environmental conditions, and functional verification and validation of specifications. The bundled uwe sun tanning beds/booths meet the requirements of the applicable FDA-recognized standards, specifically the IEC 60601-1:2005 and IEC 60601-1-2:2007 standards, and hazard analyses conforming to ISO 17491:2007 have been conducted to assure proper mitigations of risk of hazards leading to harm.

The following quality assurance measures were applied to the development of the bundled **uwe sun tanning beds/booths**:

- Risk Analysis
- Requirements Review
- Design Review
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing
- Safety testing
- Environmental testing
- Usability testing

5.4 Discussion of Clinical Tests

Clinical studies on the bundled **uwe sun tanning beds/booths** were not required in order to demonstrate the safety, effectiveness and performance of the device.

5.5 Conclusions demonstrating Safety, Effectiveness and Performance:

Based on its years of experience in the marketplace of the United States of America and the information provided in this submission, PC Marketing, Inc. concludes that the bundled **uwe sun tanning beds/booths** are safe, effective and substantially equivalent to the predicate devices.

End of 510(k) Summary