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

March 4, 2016

Sun Capsule, Inc.
Ms. Susan Anthoney-DeWet
Aegis Regulatory, Inc.
2424 Dempster Drive
Coralville, IA 52241

Re: K152238
Trade/Device Name: Sun Capsule 60/220/1.9/6
Sun Capsule 60/225/2.0/6
Sun Capsule 54/225/2.0/5.5
Sun Capsule 54/220/1.9/5.5
Sun Capsule 54/200/1.8/6
Sun Capsule 54/160/1.8/6
Sun Capsule 49/225/2.0/5.5
Sun Capsule 49/220/1.9/5.5
Sun Capsule 48/220/1.9/6
Sun Capsule 48/200/1.8/6
Sun Capsule 48/180/1.9/6
Sun Capsule 48/160/1.8/6
Sun Capsule 44/180/2.0/5.5
Sun Capsule 44/180/1.9/5.5
Sun Capsule 39/180/1.9/5.5
Regulation Number: 21 CFR 878.4635
Regulation Name: Ultraviolet lamp for tanning
Regulatory Class: Class II
Product Code: LEJ
Dated: February 26, 2016
Received: March 3, 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" (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)*
K152238

Device Name
Suncapsule Tanning Booth Devices(All Models)

Indications for Use *(Describe)*
The Suncapsule Tanning Booth devices (All Models) are intended to provide ultraviolet light exposure to male and female users over the age of 18 years to produce 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)*

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

K152238

Submission Date: August 18, 2015

1. Submitter Information:

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2. General Information:

2.1 Regulation Description: Sunlamp products and ultraviolet lamps intended for use in sunlamp products.

2.2 Common/Usual Name: Booth, Sun Tan

2.3 Proprietary Names:

Sun Capsule 60/160/1.8/6
Sun Capsule 60/220/1.9/6
Sun Capsule 60/225/2.0/6
Sun Capsule 54/225/2.0/5.5
Sun Capsule 54/220/1.9/5.5
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Sun Capsule 44/180/2.0/5.5
Sun Capsule 44/180/1.9/5.5
Sun Capsule 39/180/1.9/5.5

2.4 Classification: Class II, Special Controls

2.5 Classification Number: 878.4635

2.6 Product Code: LEJ

3. Device Description:

All Sun Capsule models are stand up booths utilizing UV fluorescent lamps arranged on upright walls in a hexagon pattern. Some models also include an optional changing booth. Standard industry construction materials are used including steel trusses, particle board, lighting components, pop rivets, etc. There are no unique materials other than the lamps which use length and diameter combinations that are unique to the tanning industry and not used for general lighting.

The number, length, and operating parameters of the lamps of each model differ in order to shorten or lengthen the exposure time desired by the purchaser. Each of the six walls constitutes a lighting fixture containing the lamps, sockets, ballast, wire, connectors and components associated with the lamp sizes required for the particular model. There are no other differences between the models.

A digital control timer module is used to program exposure times and the booths are utilized only with included protective eyewear, as outlined in 21 CFR 1040.20 (c).

4. Intended Use:

The Suncapsule Tanning Booth devices (All Models) are intended to provide ultraviolet light exposure to male and female users over the age of 18 years to produce a tanning response in the skin.

5. Predicate Device:

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

Primary Predicate Device: *All devices listed in Section 2.3 of this 510k Summary-ACCESSION NUMBER: 1531591-000.

Secondary Predicate Devices:

1. Sun Capsule Tanning Booths 1& 2, Suncapsule, Inc, K871237: 1987

*All of the devices included in this submission existed and were 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 primary predicate devices are identical to the proposed Sun Capsule Tanning Booth devices and no differences exist between the devices.

The secondary predicate device differs from the proposed Sun Capsule Tanning Booth devices in that the proposed devices have additional safety features and newer components but have the same intended use as the predicate device; have the same technological characteristics as the predicate device 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 Sun Capsule Tanning Booth devices (All Models)
have been tested and conform to national and international consensus standards:

NATIONAL AND 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))

SAFETY-SPECIFIC TO SUNLAMP PRODUCTS :

No recognition number found.

UL 482: Standard for Portable Sun/Heat Lamps Edition: 9

Devices have also been tested under and are in compliance with:

FDA PERFORMANCE STANDARDS:

- 21 CFR 1040.20 (Performance Standard For Sunlamp products and ultraviolet lamps intended for use in sunlamp products)

Specific performance testing (spectral analysis) data is submitted in this application for each device that measured irradiance to ensure compliance with radiation limits set out in 21 CFR 1040.20.

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.