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

May 20, 2016

Sunfire Industries Inc.
% Mr. Greg Bender
Managing Member
Bender & Bender Project Management Services LLC
3678 Gould Dr.
Carmel, Indiana 46033

Re: K152423
Trade/Device Name: Sunfire 32 Tanning Bed; Sunfire 24 Tanning Bed; Sunfire 16 Tanning Canopy; Sunfire 12r Tanning Canopy
Regulation Number: 21 CFR 878.4635
Regulation Name: Ultraviolet Lamp For Tanning
Regulatory Class: Class II
Product Code: LEJ
Dated: April 14, 2016
Received: April 19, 2016

Dear Mr. Bender:

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)*
K152423

Device Name
Sunfire 32, Sunfire 24, Sunfire 16, Sunfire 12R

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.

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1-800-817-5083
4905 Highway 70 East ● New Bern, NC 28562 ● Fax # (888) 253-0994

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

Device Name	Sunfire 32, Sunfire 24, Sunfire 16, Sunfire 12R	
Submitters name/contact details	Sunfire Industries Inc. 4905 Hwy 70 E. New Bern, NC 28562 Contact Details: Doug Tyler President Tel: 800-552-4446 Fax: 888-253-0994	
Summary Preparation Date	31st July 2015	
Device Name & Classification	Trade Name: Common Name: Classification Name: Device Classification: Product Code:	Sunfire 32, Sunfire 24, Sunfire 16, Sunfire 12 Tanning Bed Ultraviolet lamp for tanning Class II, 21 CFR 878.4635 LEJ
Intended Use:	The device is intended to be used for the tanning of human skin.	

Device Description:

The Sunfire series of tanning beds is available in four configurations;

a 32 lamp configuration that contains sixteen 71 inch fluorescent UV lamps in its canopy section and sixteen 71 inch fluorescent UV lamps in its bench sections,

a 24 lamp configuration that contains twelve 71 inch fluorescent UV lamps in its canopy section and twelve 71 inch fluorescent UV lamps in its bench sections,

a 16 lamp configuration that contains eight 71 inch fluorescent UV lamps in its canopy section and eight 71 inch fluorescent UV lamps in its bench sections,

and a 12 lamp canopy only configuration that contains twelve 71 inch fluorescent UV lamps.

Each configuration consists of a metal structure with lamps horizontally arranged in a manner so that they are equidistant from the tanner. The user of the Sunfire 32, 24 and 16 units lies down on the bench section and pulls down the canopy section, which is counterweighted by gas springs so that it can pivot and remain at any angle. The user of the Sunfire 12R lies down on a cot or bed and positions the Sunfire 12R canopy over their body. The lamps are powered by electronic type ballasts. The duration of exposure is controlled by a user settable electronic timer or alternatively an electromechanical timer. The session time can be set to any value called for on the recommended exposure schedule. Session time cannot be set longer than the maximum recommended exposure schedule time. A backup timer is provided that ensures the bed's lamps cannot operate longer than the maximum recommended exposure. A stop switch or knob is provided to immediately turn off the UV lamps if needed.

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The dosage of UV irradiation is within allowable limits set by the FDA performance standard 21 CFR 1040.20 and FDA Guidance letter dated August 21st 1986 titled Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products.

Predicate Devices	Sunfire Industries Inc. Models Sunfire 32, Sunfire 24, Sunfire 16 and Sunfire 12R May 6, 2014 Per Federal Register Vol. 79, No 105 Monday, June 2, 2014 Page 31212 Section IV Premarket Notification. (Docket No. FDA-2013-N-0461) "any 510(k)-exempt sunlamp product or UV lamp intended for sale on or before September 2, 2014, can serve as predicates for substantial equivalence purposes." Therefore, the Sunfire 32, 24,16 and 12R series will serve as their own predicates as they were on the market prior to September 2, 2014. The Initial Product Report for the Sunfire 24 and 16 was given accession reference number 1410322-000. The Product Report for the Sunfire 32 and 12R was given accession reference number 1410322-001.
Comparison of Characteristics	The Sunfire 32, Sunfire 24, Sunfire 16 and Sunfire 12R are identical to the units described in the submitted product reports, (FDA accession# 1410322-000 and 1410322-001) except that; the mechanical timer is now supplemented by a separate back-up timer to guard against failure of the main timer, the alternate electronic timer has a built-in back-up timer, UV Irradiance testing was performed on all lamp configurations to establish the exposure schedule per FDA Guidelines. (refer to performance testing below) The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use and performs comparably to the existing device. The Sunfire 32, Sunfire 24, Sunfire 16 and Sunfire 12R are considered substantially equivalent to the same model name predicate devices. Labeling, Device labeling and user manual contraindications and warnings for both configurations are in compliance with the requirements of 21 CFR 1040.20 and have been updated to comply with the recently updated regulation 21 CFR 878.4635. See *Proposed Labeling* section of this submittal.
Performance Testing (non-Clinical)	Results of the UV irradiance testing performed on all lamp configurations confirm that the dosage is within allowable limits set by the FDA performance standard 21 CFR 1040.20 and FDA Guidance letter dated August 21st 1986 titled Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products. The following additional factors were tested and/or evaluated. - Timer Software Validation and Verification - Biocompatibility of surfaces in contact with the tanner. - Electromagnetic compatibility and electrical safety. - Temperature of contact surfaces and temperature of air within tanning booth during operation.

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The results from these performance evaluations demonstrate the Sunfire 32, Sunfire 24, Sunfire 16 and Sunfire 12R tanning beds meet the acceptance criteria defined in the performance standard and perform comparably to the predicate device.

User Training

Sunfire will establish a training program to ensure that each purchaser of equipment intended for home use comprehends the information presented on the device's labeling.
Home use tanning equipment sold by Sunfire will ship with its control system disabled, preventing the equipment's use until a training program is completed. The training program will cover the following topics at a minimum.

1. Use of the exposure schedule to correctly define skin type and choose the appropriate session time to avoid overexposure (sunburn).
2. Repeated exposure and especially overexposure can lead to skin aging and skin cancer.
3. Importance of wearing approved eyewear to avoid injury to eyes.
4. Contraindicated for people under 18 years old.
5. Contraindicated when skin lesions or open wounds are present.
6. Should not be used by those with skin cancer or have a family history of skin cancer.
7. Allow time between tanning sessions for a tan to develop before tanning again.