DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 6, 2017

Sportarredo Group S.C.
% Rhonda Alexander
Senior Regulatory Specialist
Registrar Corp.
144 Research Dr.
Hampton, Virginia 23666

Re: K161394
Trade/Device Name: HPO Exotic, Lp1, Lp2, Lp3, MasterSun 360, MasterSun 360 New Reflector, Vega Lux
Regulation Number: 21 CFR 878.4635
Regulation Name: Ultraviolet Lamp For Tanning
Regulatory Class: Class II
Product Code: LEJ
Dated: May 13, 2016
Received: May 19, 2016

Dear Rhonda Alexander:

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 -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161394

Device Name
HPO Exotic, LP1, LP2, LP3, MasterSun 360, MasterSun 360 New Reflector, Vega Lux

Indications for Use *(Describe)*
Sunlamp product intended for use 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.

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510(k) Summary (21 CFR 807.92)

I. SUBMITTER

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Phone Number: +39 0421 767676
Date Prepared: April 15, 2016

II. DEVICE

Names of Devices:	HPO Exotic LP1 LP2 LP3 Mastersun 360 Mastersun 360 New Reflector Vega Lux
Common or Usual Name:	Booth, Sun Tan
Regulatory Class:	Class II
Product Code:	LEJ

III. PREDICATE DEVICE

Per the special controls for these devices, the predicate devices are devices which were legally offered for sale on or before September 2, 2014, but which were 510(k) exempt. Thus, the submitter has compared the subject devices to similar models of suntan beds, named as follows (along with the corresponding radiation safety report accession number):

K152233	HPO (08-9921019) LP1 (9922711-002) LP2 (9721344-006) LP3 110 -140 (9721344-005) Mastersun 360/Mastersun 360 new Reflector (15-9721345) Vega Lux Open (09-9921019)

No reference devices were used in this submission.

Prior Submissions:	These devices were previously cleared under k-number **K152233.**

DEVICE DESCRIPTION

HPO Exotic

This model is a high pressure stand up appliance with tanning lamps located in four vertical columns. The high pressure lamps have a double filter: one blue cobalt filter in the inner part and one acrylic filter in the outer. The 1000 W lamps have an additional clear glass filter between the blue filters and the acrylic. The body frame is all in metal and it closes where it is possible all the electrical components. The body frame is covered by plastic thermoformed panels.

LP1

These suntan beds are three models with the same frame, aesthetic and with many common electrical parts. All the beds use the same low pressure lamps, the difference is the presence or not of the facial lamps.

There are three versions:

LP1-32/32EL: suntan bed with only low pressure lamps, 16 in the canopy and 16 in the base

LP1-35/35EL: suntan bed with 16 low pressure lamps in the base and 16 low pressure lamps in the canopy. In the canopy is mounted one high pressure facial lamp.

LP1-45/45EL: suntan bed with 16 low pressure lamps in the base and 16 low pressure lamps in the canopy. In the canopy are mounted two high pressure facial lamps.

In all models the low pressure lamps are separated from the person by acrylic panels (3mm thickness for the canopy and 5mm thickness for the base). The high pressure lamps have a double glass filter, one blue cobalt filter in the inner part and one clear filter in the outer. Every blue filter has a control switch. If the door is opened during the session or the filters are removed, the control switch interrupts the power supply on the control board and all lamps switch off.

The body frame is all in metal and it closes where it is possible all the electrical components. The body frame is covered by plastic thermoformed panels.

LP2

This model is a bed with low pressure lamps in the canopy and in the base. The facial has 3 high pressure lamps. The low pressure lamps are separated from the person by acrylic panels (3mm thickness for the canopy and 5 mm thickness for the base). The high pressure lamps have a double glass filter: one blue cobalt filter in the inner part and one clear filter in the outer. Each blue filter has a control switch. If the door is opened during the session or the filter breaks the control switch interrupts the power supply and the lamp switches off.

LP3

These suntan beds are two models with the same frame, aesthetic and with many common electrical parts. The new models are similar to the current LP3, only the number of lamps was changed.

There are two models:
LP3-110: suntan bed with 42 low pressure lamps, 18 in the base and 24 in the canopy. The facial has four 600W (Kalfasun 630F) high pressure lamps.
LP3-140: suntan bed with 48 low pressure lamps, 20 in the base and 28 in the canopy. The facial has two 600W (Kalfasun 630F) and two 1500W (Kalfasun 1530F) high pressure lamps. Both models are beds with low pressure tanning lamps in the canopy and in the base and high pressure lamps in the facial area. The low pressure lamps are separated from the person by acrylic panels (3mm thickness for the canopy and 8mm thickness for the base). The high pressure lamps have a double glass filter: one blue cobalt filter in the inner part and one clear filter in the outer.

Mastersun
This model is a bed with a high pressure tanning lamps located in five horizontal columns placed around the person body. Three columns are in the canopy, and two are in the bed, under the acrylic panel (8mm thickness). The high pressure lamps have a double glass filter one blue cobalt filter in the inner part and one clear filter in the outer.

Vega
This model is a booth with low pressure lamps: the machine is mainly composed of three curved panels, two fixed and one is the door. Each panel has a set low pressure lamps separated from the person by acrylic panels.

The associated sunlamps include:

HPO Exotic:	BLV - Germany MHLF 630 (Kalfasun 630 F) 23470401 BLV - Germany MHLF 1530 (Kalfasun 1530 F) 23480601
LP1:	BLV - Germany MHLF 630 (Kalfasun 630 F) 23470401 Lighttech - Hungary B23-S White 100W Lighttech - Hungary B14-S White 100W Cosmedico - Germany Cosmostar Longlife 100W
LP2:	BLV - Germany MHLF 630 (Kalfasun 630 F) 23470401 Lighttech - Hungary B23-S White 100W Lighttech - Hungary B25-S White 160W
LP3:	BLV - Germany MHLF 630 (Kalfasun 630 F) 23470401 BLV - Germany HLF 1530 (Kalfasun 1530 F) 23480601 Lighttech - Hungary B23-S White 100W Lighttech – Hungary B25-S White 160W
Mastersun:	BLV - Germany MHLF 630 (Kalfasun 630 F) 23470401 BLV - Germany MHLF 640 (Kalfasun 640 F) 234720 01 BLV - Germany MHLF 1530 (Kalfasun 1530 F) 23480601 BLV - Germany MHLF 1540 (Kalfasun 1540 F) 234820
01 Vega:	Lighttech - Hungary B23-S White 160W

The associated protective eyewear:

Ultra Sunglobes – World SunCare Products, Ltd – England

IV. INDICATIONS FOR USE

Sunlamp product intended for use to tan the skin.

V. SUMMARY OF COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject and predicate devices are identical.

VI. PERFORMANCE

The subject devices were tested to be in conformity with Performance Standard 21 CFR 1040.20. They are identical to the predicate.

Usability data is included with the submission to support the conversion of indications from Rx to OTC.

Biocompatibility testing

The subject devices are categorized as surface devices which only come into contact with intact skin for a duration of less than 24 hours. The only material that comes into contact with the patient's skin is the polymethyl methacrylate (PMMA), which has been shown to be biocompatible via European standard 30993 (which corresponds to ISO 10993).

No additional biocompatibility testing was done, as the devices are identical to the predicate in every way.

Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted on all devices, which were shown to pass the tests conducted.

No additional electrical or electromagnetic testing was performed, as the devices are identical to the predicate in every way.

Software Verification and Validation Testing
Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

VII. CONCLUSIONS

Since the subject and predicate devices are identical technologically, with few minor aesthetic differences, we conclude that the change in intended use from prescription to over-the-counter does not negatively affect a finding of substantial equivalence between the devices and predicates.