



Food and Drug Administration  
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January 27, 2016

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

Re: K152233

Trade/Device Name: B-Phase, 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: August 6, 2015

Received: August 7, 2015

Dear Ms. 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 -S**

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

## Indications for Use

510(k) Number (if known)

K152233

Device Name

BPhase, 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)

**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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## 510(k) Summary (21 CFR 807.92)

### I. SUBMITTER

Sportarredo Group S.C.  
Via dell' Industria 7  
Gruaro, Venice  
30020 Italy

Contact Person: Stefano Iridio, Area Sales Manager (s.iridio@sportarredousa.com)  
Date Prepared: August 4, 2015

### II. DEVICE

Names of Devices:	BPhase 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):

B-Phase (9921019-012)  
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. No prior submissions exist for the subject devices.

#### **IV. DEVICE DESCRIPTION**

##### **B-Phase**

This model is a low pressure stand up unit with UV low pressure lamps. The lamps are located in four vertical columns and the columns are located surrounding the persons who use the equipment. Visible red-light lamps have been installed in the same columns, on the other side of the internal metallic structure. A rotating system lets the column show alternatively the UV lamps or the red-light lamps. The control board lets the user choose which lamps are going to be used during the session. This device includes a foot massager.

##### **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

## **V. INDICATIONS FOR USE**

Sunlamp product intended for use to tan the skin.

## **VI. SUMMARY OF COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE**

The subject and predicate devices are nearly identical technologically, with few minor aesthetic differences. The differences which exist do not negatively affect a determination of substantial equivalence.

## **VII. PERFORMANCE**

The devices were tested to be in conformity with Performance Standard 21 CFR 1040.20.

### **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).

### **Electrical safety and electromagnetic compatibility (EMC)**

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

### **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.

## **VIII. CONCLUSIONS**

Since the subject and predicate devices are nearly identical technologically, with few minor aesthetic differences, we conclude that the subject devices are substantial equivalent to the predicate devices.