ProSun International LLC
Jennifer Henkemans
COO- Chief Operating Officer
2442 23rd Street North
Saint Petersburg, Florida 33713

Re: K181455
Trade/Device Name: ProSun sunlamp products, Luxura sunlamp products
Regulation Number: 21 CFR 878.4635
Regulation Name: Ultraviolet Lamp For Tanning
Regulatory Class: Class II
Product Code: LEJ
Dated: May 31, 2018
Received: June 4, 2018

September 10, 2018

Dear Jennifer Henkemans:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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
medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for
devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see
https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good
manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820)
for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if
applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-
1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including
information about labeling regulations, please see Device Advice
(https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn
(http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and
Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website
(http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone
(1-800-638-2041 or 301-796-7100).

Sincerely,

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
Device Name
Lumina, Prosun, Luxura, Onyx, Jade, Sundream

Indications for Use (Describe)
Tanning Bed Systems are intended to provide tanning of the 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.

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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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASstaff@fda.hhs.gov

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1.5 – 510(k) Summary

NON-CONFIDENTIAL SUMMARY OF SAFETY and EFFECTIVENESS
In accordance with the requirements of the Safe Medical Device Act, FDA 21 CFR 807.92(c), ProSun International, LLC herein submits this Summary of Safety and Effectiveness for the Lumina, Prosun, Luxura, Onyx, and Jade sunlamp tanning bed product lines.

Submitter Information:
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Saint Petersburg, Florida 33713-4018
Tel - 727-825-0400 Fax – 727-825-0700

Official Contact:
Jennifer C. Henkemans, Chief Operating Officer
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jenniferh@prosun.com

Regulatory Consultant:
N/A

Date Prepared:
May 31, 2018

1.5.1 – PROPOSED DEVICE IDENTIFICATION

All proposed devices have originally been listed as Class I devices (510(k) exempt sunlamp product) and legally offered for sale before September 2, 2014. In accordance with the final order (Federal Register, Volume 79, Number 5) these proposed devices are used as predicate devices for substantial equivalence purposes.

Device Trade Name: ProSun sunlamp products
Common Name: ProSun sunlamp products
Classification Name: Booth, Sun Tan (21 CFR 878.4635, Product Code LEJ)
Classification Panel: General & Plastic Surgery
Device Class: Class II
The following table presents the proposed ProSun sunlamp products. The Jade, Onyx, RelaxSun and ProSun sunlamp products represent technically and fundamentally the same basic products which do not alter any technical specifications or aspects of the devices.

<table>
<thead>
<tr>
<th>Current Model</th>
<th>Historical Model</th>
<th>Marketing Name</th>
<th>Brand and Type Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>24 Series</td>
<td>12 V</td>
<td>ProSun Canopy Tanner</td>
</tr>
<tr>
<td>24</td>
<td>24 Series</td>
<td>RelaxSun 24</td>
<td>RelaxSun 24</td>
</tr>
<tr>
<td>24J</td>
<td>24 Series</td>
<td>JADE 24</td>
<td>ProSun Jade 24</td>
</tr>
<tr>
<td>28</td>
<td>28 Series</td>
<td>ONYX 28</td>
<td>ProSun ONYX 28</td>
</tr>
<tr>
<td>32J</td>
<td>32 Series</td>
<td>JADE 32</td>
<td>ProSun Jade 32</td>
</tr>
<tr>
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<td>32 Series</td>
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<td>ProSun ONYX 32</td>
</tr>
<tr>
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</tr>
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<td>ONYX 32 SLi</td>
<td>ProSun ONYX 32 SLi Intensive (160)</td>
</tr>
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<td>36 Series V</td>
<td>V1</td>
<td>ProSun V1</td>
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<td>42V3</td>
<td>42 Series V</td>
<td>V3</td>
<td>ProSun V3 42 XLc High Intensive</td>
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**Device Trade Name:** Luxura sunlamp products  
**Common Name:** Luxura sunlamp products  
**Classification Name:** Booth, Sun Tan (21 CFR 878.4635, Product Code LEJ)  
**Classification Panel:** General & Plastic Surgery  
**Device Class:** Class II

The following table presents the Luxura sunlamp products. The Luxura sunlamp products represent technically and fundamentally the same basic products which do not alter any technical specifications or aspects of the devices.

<table>
<thead>
<tr>
<th>Current Model</th>
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<th>Marketing Name</th>
<th>Brand and Type Name</th>
</tr>
</thead>
<tbody>
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<td>Luxura 34 SLi Intensive</td>
</tr>
<tr>
<td>36X</td>
<td>36 Series</td>
<td>X3 (120)</td>
<td>Luxura 36 SLi High Intensive</td>
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<td>36X-P</td>
<td>36 Series</td>
<td>X3 (180)</td>
<td>Luxura 36 SLi High Intensive</td>
</tr>
<tr>
<td>38X</td>
<td>38 Series</td>
<td>X5</td>
<td>Luxura 38 SLi High Intensive</td>
</tr>
<tr>
<td>42X</td>
<td>42 Series</td>
<td>X7</td>
<td>Luxura 42 SLi High Intensive</td>
</tr>
<tr>
<td>42V6</td>
<td>42 Series V</td>
<td>V6</td>
<td>Luxura 42 XL Ultra Intensive</td>
</tr>
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<td>V8 E</td>
<td>Luxura V8 48 E-Power</td>
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<td>52X/VEGAZ</td>
<td>52 Series</td>
<td>X10/VEGAZ</td>
<td>Luxura X10/VEGAZ</td>
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</table>
1.5.2 – DEVICE CLASSIFICATION

Classification Name: Booth, Sun Tan (21 CFR 878.4635, Product Code LEJ)
Classification Panel: General & Plastic Surgery
Device Class: Class II

1.5.3 – DEVICE DESCRIPTION

The primary technical components of sunlamp products are whole body tanning devices consisting of a mechanical frame with Ultraviolet (UV) lamps providing an artificial source of UV radiation. The UV light is intended for irradiation of the human body to induce skin tanning. The user of the proposed devices device either lies in the horizontal tanning bed or stands in the vertical tanning booth.

Skin tanning varies with skin type and as the UV sources intensities with characteristic UV-A and UV-B proportions result in cosmetic tanning of the human skin.

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

1.5.4 – INTENDED USE

Tanning Bed Systems are intended to provide tanning of the human skin.

1.5.5 – PREDICATE & SUBSTANTIAL EQUIVALENCE DEVICES

All proposed devices have originally been listed as Class I devices (510(k) exempt sunlamp product) and legally offered for sale before September 2, 2014. In accordance with the final order (Federal Register, Volume 79, Number 5) these proposed devices are used as predicate devices for substantial equivalence purposes.

1.5.6 – COMPARISON TO PREDICATE & SUBSTANTIAL EQUIVALENCE DEVICES

The following table represents the technological characteristics and parameters of the proposed devices.
## 1.5.6 – COMPARISON TO PREDICATE & SUBSTANTIAL EQUIVALENCE DEVICES

The previous and following table represents the technological characteristics and parameters of the identified predicate devices and proposed devices. The Proposed Devices and the Predicate...
Devices are the same devices which are unchanged and are totally equal. Therefore the list of Proposed Devices equals the Predicate Devices which are listed as follows.

<table>
<thead>
<tr>
<th>New Model</th>
<th>Model</th>
<th>Marketing</th>
<th>Brand and Type</th>
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<td>Canopy Tanner</td>
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<td>JADE 24</td>
<td>Jade 24</td>
<td>Prosun 24 Series</td>
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<td>9520183-04</td>
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<td>RelaxSun 24</td>
<td>Prosun 24 Series</td>
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<td>ONYX 28</td>
<td>Onyx 28</td>
<td>Prosun 28 Series</td>
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<td>32/1</td>
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<td>36</td>
<td>V1</td>
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<tr>
<td>42V3</td>
<td>42</td>
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<td>Prosun 42 Series</td>
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<tr>
<td>42V6</td>
<td>42</td>
<td>V6</td>
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<tr>
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<td>V8</td>
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<td>Luxura 48 Series</td>
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<td>9922525-00</td>
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<td>X10/VEGAZ</td>
<td>Luxura X10/VEGAZ</td>
<td>Prosun 52 Series</td>
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<td>9922524</td>
<td>K944015</td>
</tr>
</tbody>
</table>
1.5.7 – SUMMARY OF PERFORMED TESTS

The proposed devices have been non clinically tested in accordance with:

- Biocompatibility and in accordance with DIN EN ISO 10993
- Electrical and mechanical safety in accordance with IEC 60601-1 (IEC 60335-2-27 and UL 482)
- EMC in accordance with IEC 60601-1-2 (CISPR 14-1 and 14-2)
- Spectral emissions of all sunlamp products were measured. The test procedure for measuring the spectral emission is in accordance with IEC 6033-2-27 and 21 CFR 1002, 1010 – 1050).
- Irradiance ratio limits of all proposed sunlamp products are in accordance with 21 CFR 1040.2(c)(1).
- Software verification & validation testing according to FDA’s “Guidance for the Content of Premarket Submission for Software Contained in Medical Devices”
- The maximum timer intervals and exposure schedules have been determined according to FDA’s “Policy on maximum timer interval and exposure schedule for sunlamp products.”
- Performance Standards testing in accordance with 21 CFR 1040.20

1.5.8 – CONCLUSION

PROSUN INTERNATIONAL LLC believes that based on analysis of the technological characteristics based on non-clinical performance data and historical field experience based on the same indications for use PROSUN INTERNATIONAL LLC believes the ProSun, Lumina, Luxura, Onyx, and Jade sunlamp products are substantially equivalent to currently legally marketed predicate devices. All Special Controls for Class 2 EMDRM as defined by the FDA are fulfilled. These devices do not introduce new Indications For Use, they have the same technological characteristics and do not introduce any new issues of potential hazards, safety risks, effectiveness or usability.