December 10, 2021

Ultrasun International B.V.
℅ Shepard Bentley
President & Principal Consultant
Bentley Biomedical Consulting, LLC
28241 Crown Valley Parkway, Suite 510(k)
Laguna Niguel, California 92677

Re: K210004
Trade/Device Name: i8 Tanning Booth
Regulation Number: 21 CFR 878.4635
Regulation Name: Sunlamp Products And Ultraviolet Lamps Intended For Use In Sunlamp Products
Regulatory Class: Class II
Product Code: LEJ
Dated: December 28, 2020
Received: January 4, 2021

Dear Shepard Bentley:

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 801); 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Purva Pandya
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210004

Device Name
i8 Tanning Booth

Indications for Use *(Describe)*
The i8 tanning booth is an over-the-counter tanning device emitting ultraviolet light in the UVB and UVA region of the spectrum for the tanning of the human skin of an adult person.

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.

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510(k) SUMMARY

(according to 21 CFR §807.92)

1. **GENERAL INFORMATION**

Submitter:	**Ultrasun International B.V.**
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	The Netherlands
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Official Correspondent:	**Shepard G. Bentley, RAC**
	Bentley Biomedical Consulting, LLC
	28241 Crown Valley Parkway, Suite 510(k)
	Laguna Niguel, CA 92677
	Phone: (949) 374 – 9187
	Email: sbentley@bentleybiomed.com

Preparation Date:	**December 6, 2021**

2. **SUBJECT DEVICE**

Device Name:	**i8 Tanning Booth**
Classification Name:	**Booth, Sun Tan**
Product Code:	**LEJ (21 CFR §878.4635)**
Classification Panel:	**General Surgery Devices (DHT4A)**
Device Class:	**Class II – Special Controls**

3. **PREDICATE DEVICE**

Device Name:	**IBL 5000 Tanning Booth**

Classification Name: Booth, Sun Tan

Product Code: LEJ (21 CFR §878.4635)

Classification Panel: General Surgery Devices (DHT4A)

Device Class: Class II – Special Controls

510(k) Number: K152405

4. DEVICE DESCRIPTION

Ultrasun International B.V. i8 Sun Tanning Booth is a tanning device consisting of a mechanical structure equipped with artificial light sources using ultraviolet light technology, which produces ultraviolet radiation within the UVA and UVB ranges. The UV light is intended to induce skin tanning. The user stands within the unit.

5. INDICATIONS FOR USE

The i8 tanning booth is an over-the-counter tanning device emitting ultraviolet light in the UVB and UVA region of the spectrum for the tanning of the human skin of an adult person.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

	Subject Device	Predicate Device	Evaluation
Device Trade Name	i8	IBL 5000	-
Number of Lamps	48 x +200W	50 x +200W	similar
Watts (Max Unit Power)	9600 Watts	10,000 Watts	similar
Maximum Exposure Time	12 minutes / session	12 minutes / session	same

7. PERFORMANCE DATA

- Electrical and mechanical safety testing in accordance with IEC 60601-1:2005 + A1:2012
- Electromagnetic compatibility testing in compliance with IEC 60601-1-2:2007
- Software development per IUC 62304:2016

8. CONCLUSION

Based on an analysis of the technological characteristics, non-clinical performance data, and indication for use, Ultrasun International B.V. believes that the subject device is substantially equivalent to the legally marketed predicate device, and does not raise any new issues of safety and effectiveness.