



January 16, 2026

Solius Labs, Inc.  
% Shepard Bentley  
Regulatory Consultant  
Bentley Biomedical Consulting, LLC  
28241 Crown Valley Parkway  
Suite 510(k)  
Laguna Niguel, California 92677

Re: K252960

Trade/Device Name: SOLIUS PRO UVB Light Panel

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: SGZ

Dated: September 15, 2025

Received: September 16, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**TANISHA L.** Digitally signed by  
**HITHE -S** TANISHA L. HITHE -S  
Date: 2026.01.16  
15:33:00 -05'00'

Tanisha Hithe  
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

## Indications for Use

510(k) Number (if known)  
K252960

Device Name  
SOLIUS PRO UVB Light Panel

Indications for Use (Describe)

SOLIUS PRO is an over-the-counter (OTC) light panel intended to stimulate production of Vitamin D in people 22 years and older.

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.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 510(k) Summary – K252960

### I. SUBMITTER

SOLIUS Labs, Inc.  
100 Ravine Lane, Suite 310  
Bainbridge Island, WA 98110  
Ph: 202-487-3825

Contact Person: Shepard G. Bentley, RAC  
Regulatory Consultant  
Ph: 949-374-9187  
Email: shepbentley@gmail.com

Date Prepared: January 16, 2026

### II. DEVICE

Name of Device: SOLIUS PRO UVB Light Panel  
Common or Usual Name: Ultraviolet Light Therapy Device Classification Name: Ultraviolet lamp  
Regulation Number: 21 CFR 878.4635  
Regulatory Class: Class II  
Product Code: SGZ

### III. PREDICATE DEVICE

Name of Device: Sperti Sun Lamp Model P-164  
Regulation Number: 21 CFR 878.4635  
Regulatory Class: Class II (pre-amendment device, now regulated as Class II)  
Product Code: RAB

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

The SOLIUS PRO is a portable, over-the-counter (OTC) photobiomodulation light panel designed for home or facility use. The device stimulates vitamin D production through controlled exposure of a targeted ultraviolet B (UVB) spectrum ranging from 280-315 nm. Specialized UVB LEDs deliver a controlled UVB emission aligned with the action spectrum for vitamin D synthesis while incorporating multiple technological and software safety features.

The SOLIUS PRO provides a uniform light output across an area of exposed skin on the torso to optimize vitamin D production while minimizing unnecessary exposure to the face and eyes. A height-adjustable hanging system positions the panel at shoulder level, and an integrated distance sensor ensures the user maintains the optimal distance for both safety and effectiveness.

Before the first therapy session, the Personalized Dosing System uses a built-in optical sensor to quantifiably measure the Individual Typology Angle degree of the user's skin and a user response to a skin history question. The system calculates a personalized dose below 1 Minimal Erythema Dose (MED) that is delivered for a precisely controlled exposure time to stimulate vitamin D production and mitigate the risk of erythema.

Therapy sessions are initiated and monitored through a mobile application. The mobile application enforces the use of the provided protective eyewear by performing a facial scan before a session can begin. Once therapy begins, the system provides real-time visual and audio feedback from the distance sensor to assist user positioning. The mobile application records dosing information and user feedback and manages session scheduling and dose adjustments to ensure safe operation.

#### **V. INDICATIONS FOR USE**

SOLIUS PRO is an over-the-counter (OTC) light panel intended to stimulate production of vitamin D in people 22 years and older.

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

SOLIUS PRO is substantially equivalent to the Sperti Sun Lamp Model P-164 predicate device. The detailed comparison between the Subject Device and the Predicate devices is provided in Table 1 below. SOLIUS PRO uses the same fundamental mode of action as the predicate (UVB stimulated vitamin D production) with additional safety controls to meet or exceed relevant safety standards.

**Table 1. Comparison of the SOLIUS PRO light panel (subject device) and the Sperti (predicate device).**

	<b>SOLIUS PRO UVB Light Panel</b> (subject device)	<b>Sperti Sun Lamp Model P-164</b> (predicate device)	<b>Substantial Equivalence Comparison</b>
<b>Classification</b>	Class II	Class II (Pre-amendment device)	N/A
<b>510(k) Number</b>	K252960	No 510(k) clearance	N/A
<b>Intended Use</b>	Intended to stimulate the production of vitamin D.	Activate sterols in the skin converting them to essential Vitamin D – known as the sunshine Vitamin.	Same
<b>Indications for Use</b>	SOLIUS PRO is an over-the-counter (OTC) light panel intended to stimulate production of vitamin D in people 22 years and older.	Activate sterols in the skin converting them to essential Vitamin D – known as the sunshine Vitamin.	Similar; differences in the indications statement do not impact the safety and effectiveness, nor substantial equivalence of the device.
<b>OTC vs. Rx</b>	OTC	OTC	Same

	<b>SOLIUS PRO UVB Light Panel</b> (subject device)	<b>Sperti Sun Lamp Model P-164</b> (predicate device)	<b>Substantial Equivalence Comparison</b>
<b>Light Source and Spectrum</b>  * According to Nationally Recognized Testing Laboratory (NRTL) data.	Light Source: 132 precision UVB LEDs  Spectral peak: single narrow peak at 294 nm in UVB range targeting the vitamin D action spectrum.  Spectrum (% of total irradiance): 2.90% output @ $\geq 315 - 400$ (UVA) 96.92% output @ $\geq 280 - < 315$ (UVB) 0.18% output @ $200 - < 280$ (UVC)	Light Source: 1 Mercury Arc Lamp Bulb  Spectral peak: multiple peaks at 280, 296, 302, 312, 334, 366 nm.  Spectrum (% of total irradiance): 62.62% output @ $\geq 315 - 400$ (UVA) 36.51% output @ $\geq 280 - < 315$ (UVB) 0.88% output @ $200 - < 280$ (UVC)	Similar; both cover the 280-315 nm UVB spectrum.  Similar; SOLIUS PRO is a targeted, narrow subset of the broader Sperti light spectrum.  Different; SOLIUS PRO has one targeted light peak in the vitamin D action spectrum to maximize vitamin D production <sup>1</sup> and minimize total UVR exposure and risk of skin cancer. <sup>2</sup>
<b>Treatment Area at Intended Distance</b>	20 in x 18 in	30 in x 30 in	Similar

<sup>1</sup> CIE 174:2006 Action spectrum for the production of previtamin D3 in human skin.

<sup>2</sup> Non-Melanoma Skin Cancer (NMSC) Action Spectrum according to ISO standard 28077:2006.

<b>Power Source</b>	100-240 V~, 50/60 Hz, 70 VA	120 V~, 60 Hz, 400 W	Similar; SOLIUS PRO is more energy efficient and is designed to be compliant with United States and international power requirements.
<b>Total UVR Irradiance</b>  * According to Nationally Recognized Testing Laboratory (NRTL) data.	242.53 $\mu\text{W}/\text{cm}^2$	365.40 $\mu\text{W}/\text{cm}^2$	Different; performance testing demonstrates SOLIUS PRO delivers an equivalent vitamin D weighted dose with less total UVR exposure.
<b>Output Uniformity</b>  * According to Nationally Recognized Testing Laboratory (NRTL) data.	Maximum variation: 18.20% % of area with variation < -20%: 7%	Maximum variation: 125% % of area with variation < -20%: 39%	Different; performance testing demonstrates SOLIUS PRO provides tighter spatial uniformity which is intended to improve safety.

	<b>SOLIUS PRO UVB Light Panel</b> (subject device)	<b>Sperti Sun Lamp Model P-164</b> (predicate device)	<b>Substantial Equivalence Comparison</b>
<b>NRTL Certified Medical Safety Standards</b>	<p>SOLIUS PRO meets the following safety standards:</p> <ul style="list-style-type: none"> <li>• IEC 60601-1: Electrical Safety</li> <li>• IEC 60601-1-2: Electromagnetic Compatibility (EMC)</li> <li>• IEC 60601-1-6: Usability</li> <li>• IEC 60601-1-11: Home Healthcare Environment</li> <li>• IEC 60601-2-57: Medical Light Therapy</li> <li>• IEC 60601-2-83: Home Medical Light Therapy</li> </ul>	None.	<p>Different; Sperti was developed prior to the implementation of current safety standards.</p> <p>SOLIUS PRO meets current safety standards.</p>
<b>UV Exposure Safety Guidelines</b>	<p>SOLIUS PRO is below the Threshold Limit Values (TLV) for daily Ultraviolet Radiation (UV) exposure established by <i>American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLV) 2024 for Ultraviolet Radiation (UV)</i>.</p>	<p>Sperti exceeds the Threshold Limit Values (TLV) for daily Ultraviolet Radiation (UV) exposure established by <i>American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLV) 2024 for Ultraviolet Radiation (UV)</i>.</p>	<p>Different; Sperti was developed prior to the implementation of current UV exposure safety guidelines.</p> <p>SOLIUS PRO meets current UV exposure safety guidelines.</p>

	<b>SOLIUS PRO UVB Light Panel</b> (subject device)	<b>Sperti Sun Lamp Model P-164</b> (predicate device)	<b>Substantial Equivalence Comparison</b>
<b>User Controls</b>	<p>Duration of 0 to 430 seconds (7.2 minutes), digital timer software control with redundancy.</p> <p>User creates profile in SOLIUS mobile app, completes user onboarding in app, and completes skin assessment to determine first dose. App displays therapy timer to user during therapy.</p> <p>After each dose, user must answer skin response question which is recorded and used to adjust dosing.</p>	<p>Duration of 0 to 10 minutes controlled with a manual timer, and label advises to “let your skin guide you” to adjust dose.</p> <p>User sets a manual timer (with hashmarks for 2, 4, 6, and 8 minutes) to turn on the lamp. First dose, titration, and ongoing therapies are based on label instructions and user experience.</p>	Similar; additional safety controls.
<b>Distance Monitor &amp; Control</b>	Distance sensors dynamically monitor user position to ensure user is within intended distance from light panel during therapy. Visual warning in the mobile app and audible warnings from the light panel are provided to the user when they are outside of the intended distance (too close or too far) and therapy will shut off if user does not stay within the intended distance.	Label advises a ruler to ensure user is at the intended distance from the light during therapy.	Similar; additional safety controls.

	<b>SOLIUS PRO UVB Light Panel</b> (subject device)	<b>Sperti Sun Lamp Model P-164</b> (predicate device)	<b>Substantial Equivalence Comparison</b>
<b>First Dose</b>	Software guides user through quantitative and repeatable skin measurement using a sensor and a response to a skin history question to determine a personalized dose duration below 1.0 minimal erythema dose (MED) on first therapy for all users.	Label advises all users that “initial exposure should not exceed 3 minutes.”	Similar; both devices guide initial dose while SOLIUS PRO first dose is managed by safety controls validated by performance testing which demonstrates a reduced risk of erythema.
<b>Titration</b>	Optional titration of 20% per therapy (up or down) according to American Academy of Dermatology UVB titration guidelines. <sup>3</sup>  Software records user skin response after each session and automatically reduces dose if user reports skin irritation.	Label advises “Each day increase the exposure time no more than one minute.”  Example scenarios based on label recommendations: a) First dose of 1 minute, increase one minute to 2 minutes = 100% dose increase b) Dose of 5 minutes, increase one minute to 6 minutes = 20% dose increase	Similar; additional safety controls.

---

<sup>3</sup> Elmets CA, et. al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy. J Am Acad Dermatol. 2019 Sep;81(3):775-804. doi: 10.1016/j.jaad.2019.04.042. Epub 2019 Jul 25. Erratum in: J Am Acad Dermatol. 2020 Mar;82(3):780. doi: 10.1016/j.jaad.2019.11.024. PMID: 31351884.

	<b>SOLIUS PRO UVB Light Panel</b> (subject device)	<b>Sperti Sun Lamp Model P-164</b> (predicate device)	<b>Substantial Equivalence Comparison</b>
<b>Frequency</b>	<p>Therapy calendar in the SOLIUS software User Profile tracks usage and locks out user to ensure at least 24-hour period between therapy sessions.</p> <p>This control ensures SOLIUS does not exceed daily exposure limit according to American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLV) 2024 for Ultraviolet Radiation (UV).</p>	Label advises “Exposure should not be repeated more often than once daily.”	Similar; with additional safety controls.
<b>Eyewear Enforcement</b>	Proper use of SOLIUS provided protective eyewear is confirmed by the mobile app facial scan prior to initiating a therapy session.	Label suggests wearing included protective eyewear, but it is not enforced.	Similar; with additional safety controls.
<b>Emergency Stop</b>	Accessible stop button for emergency system shutdown and pause button provided in mobile app.	User must turn the timer knob or unplug the device from the wall.	<p>Different; Sperti development was prior to the implementation of current UV exposure safety guidelines.</p> <p>SOLIUS PRO meets current UV exposure safety guidelines.</p>

## VII. PERFORMANCE DATA

The following performance data was provided in support of the substantial equivalence determination.

### Software and wireless safety:

Due to the software component and wireless functionality of the device, SOLIUS was assessed according to and in compliance with the following standard:

- IEC 62304:2006 Medical device software – Software life cycle processes
- AAMI TIR57:2016 Principles for medical device security – Risk Management

### Cleaning and reprocessing:

Cleaning validation was performed to evaluate the efficacy of the cleaning procedure for the device.

Testing was conducted in compliance with:

- ANSI/AAMI ST98:2022 Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices
- AAMI TIR12:2020 Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers
- FDA Guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff. March 17, 2015

### Packaging validation:

The packaging for the device was tested for shipping vibration and drop; no performance loss was observed in accordance with the following standard:

- ISTA 3A 2018 Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less

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

Electrical safety and EMC testing were conducted on the SOLIUS PRO light panel. The system complies with:

- IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11:2015 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (Home healthcare environment)

- IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

#### Performance testing:

Photobiologic safety testing following IEC 62471:2006 was conducted on the SOLIUS PRO light panel. The system complies with:

- IEC 60601-2-57:2023 Medical electrical equipment – Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
- IEC 60601-2-83:2019 Medical electrical equipment – Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment (Home light therapy environment)

Additional optical radiation testing at the intended treatment distance was conducted by independent test lab to ensure SOLIUS PRO light panel peak wavelength, spectral distribution, and uniformity meets the specified requirement. Testing also confirmed optical radiation output is equivalent or safer when compared to the predicate device.

- UV dose per session verified below ACGIH 2024 TLV for daily UV exposure. Only one session is allowed per day, enforced by the mobile app
- Optical output testing verified SOLIUS PRO peak wavelength is within  $293 \text{ nm} \pm 2 \text{ nm}$
- Optical output testing verified SOLIUS PRO contains  $> 95\%$  UVB (280-315 nm) content
- Optical output testing verified SOLIUS PRO output uniformity over the treatment area is within  $\pm 20\%$  when compared to the average. A decrease in output greater than 20% is only at the edge of the treatment area, and accounts for less than 20% of the treatment area.

#### Human factors:

Usability testing was conducted by Eurofins Clinical Research Laboratories using the SOLIUS PRO device, in compliance with:

- IEC 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366-1:2015 Application of usability engineering to medical devices.
- AAMI/ANSI/HE75:2009 Human factors engineering – design of medical devices.

### Dosage validation:

SOLIUS was evaluated through human use assessment conducted by third-party organizations to confirm appropriate dose control and absence of unexpected adverse skin reactions when the device is used as intended.

1. A clinical study was performed by Eurofins Clinical Research Laboratories to validate the effectiveness of the SOLIUS PRO to measure skin and administer a UVB light dose below 1 Minimal Erythema Dose (MED) with the following results:
  - 27 users across Fitzpatrick skin types I–VI were tested.
  - 96% of users received an initial SOLIUS dose below or at 1.0 MED.
  - 100% of users received the initial SOLIUS dose without reporting erythema, edema, or other adverse skin reactions.
  - No adverse events were observed.

## **VIII. CONCLUSIONS**

SOLIUS PRO UVB Light Panel is substantially equivalent to the Sperti Sun Lamp Model P-164 intended use and fundamental scientific technology (UVB exposure to stimulate vitamin D production). Differences, including LED light source, dosing personalization, and safety controls, do not raise new questions of safety or effectiveness. Performance and usability testing demonstrate that SOLIUS PRO is substantially equivalent to the predicate.