July 2, 2020

Psoria-Shield
John Yorke
General Manager
409 Mandeville St
Utica, New York 13502

Re: K192411
Trade/Device Name: Psoria-Shield AURORA
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet Lamp For Dermatologic Disorders
Regulatory Class: Class II
Product Code: FTC
Dated: June 1, 2020
Received: June 3, 2020

Dear John Yorke:

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,

Colin Kejing Chen
Acting 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 Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement on last page

510(k) Number *(if known)*

K192411

Device Name

AURORA™

Indications for Use *(Describe)*

The AURORA system is indicated for use in targeted PUVA photochemistry and UVB phototherapy for the treatment of skin conditions including psoriasis, vitiligo, atopic dermatitis (eczema), and seborrheic dermatitis. In addition, the system UVB channel is indicated for the treatment of leukoderma.

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.

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"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."

K192411

510(k) SUMMARY

Psoria-Shield Inc's AURORA System

Manufacturer: Psoria-Shield Inc.
409 Mandeville St
Utica, NY 13502, USA

Phone: 866 991 9547

Contact Person: John Yorke

Date Prepared: July 1, 2020

Trade Name: Aurora

Common or Usual Name: Ultraviolet lamp for dermatologic disorders

Classification Name: Light, Ultraviolet, Dermatological

Predicate Device

Psoria-Shield Inc's PS1000 (K103540, cleared 2011)

Purpose of the Special 510(k) Notice

The AURORA is a modification to Psoria-Shield's existing PS1000 system. Psoria-Shield has redesigned the unit to perform the same function.

Indications For Use

The AURORA system is indicated for use in targeted PUVA photochemistry and UVB phototherapy for the treatment of skin conditions including psoriasis, vitiligo, atopic dermatitis (eczema), and seborrheic dermatitis. In addition, the system UVB channel is indicated for the treatment of leukoderma.

Device Description

The Psoria-Shield AURORA system delivers UVA or UVB phototherapy to target skin areas through one of two handpieces. The handpieces are connected to a base unit which uses an air cooling system to maintain system temperature, and has a built-in touchscreen to operate the device.

Technological Characteristics

The AURORA system is a modified version of the PS1000 predicate device, and has similar technological characteristics. It uses the same energy source to deliver a UVA or UVB phototherapy to a
2.88 cm^2 target surface area.

Changes in design from the PS1000 include the following:

- An air-cooling system to prevent overheating of the system during use
- Separate handpieces to deliver UVA or UVB light
- An integrated touchscreen running on Linux operating system
- Removal of the built-in camera due to lack of customer interest
- A USB printer port has been added with software functionality allowing patient treatment data to be printed out for record keeping.

Summary Of Performance Data

Performance testing using pre-production AURORA systems demonstrated that the energy levels output from each handpiece are consistent with user-defined energy levels.

Electrical Safety Testing was successfully performed on production devices to show compliance to the following standards:

- IEC 60601-1:2005+A1:2012 *Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance*
- IEC 60601-1-2:2014 *General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*
- IEC 60601-2-57 *Medical Electrical Equipment Part 2: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use*

UV Safety Testing was successfully performed to show compliance to IEC 62471:2009 *Photobiological Safety of lamps and lamp systems.*

Software Verification: The software development and testing were executed in compliance to IEC 62304 Medical device software – Software life cycle processes and ISO 14971 Medical devices - Application of risk management to medical devices.

Substantial Equivalence

The AURORA system has the same intended use and similar indications, principles of operation, and technological characteristics as the predicate PS1000 system. As shown in the table below, the minor differences in the air cooling, operating system, addition of separate handpieces to deliver UVA or UVB phototherapy do not raise any new questions of safety or effectiveness. Performance data demonstrates that the AURORA system is as safe and effective as the predicate PS1000 system. Thus, the AURORA system is substantially equivalent to its predicate device.

Substantial Equivalence Table Comparing Subject and Predicate Devices

	Psoria-Shield Modified Device (Aurora)	**Psoria-Shield cleared PS1000**
Intended Use	The AURORA is intended to be used for the treatment of dermatologic disorders.	The PS1000 is intended to be used for the treatment of dermatologic disorders.
Indications for Use	The Psoria-Light Model AURORA is indicated for use in targeted PUVA photochemistry and UVB phototherapy for the treatment of skin conditions including psoriasis, vitiligo, atopic dermatitis (eczema), and seborrheic dermatitis. In addition, the system UVB channel is indicated for the treatment of leukoderma.	The Psoria-Light Model PS1000 is indicated for use in targeted PUVA photochemistry and UVB phototherapy for the treatment of skin conditions including psoriasis, vitiligo, atopic dermatitis (eczema), and seborrheic dermatitis. In addition, the system UVB channel is indicated for the treatment of leukoderma.
Components	- Base station - Touchscreen/GUI - Two handpieces	- Base station - Touchscreen/GUI - Handpiece
Operating System	Linux Ubuntu	Windows XP
Safety Features	Key lock to prevent accidental energy emission.	Key lock to prevent accidental energy emission.
Power Source	110V wall power	110V wall power
Dimensions	19” (W) x 14” (L) x 8” (H)	17.5” (W) x 22” (L) x 18” (H)
Weight	12lbs	60lbs
Accessories	USB-connected printer	None
Available Wavelengths	UVA (350 – 395nm) UVB (300 – 320nm)	UVA (350 – 395nm) UVB (300 – 320nm)
Minimum Power (UVA)	0.1 J/cm^2	0.4 J/cm^2
Maximum Power (UVA)	3.4 J/cm^2	5.0 J/cm^2
Minimum Power (UVB)	0.1 J/cm^2	0.015 J/cm^2
Maximum Power (UVB)	3.4 J/cm^2	3.120 J/cm^2
Treatment Area	2.88cm^2	2.88cm^2
Handpiece design	Two handpieces. One handpiece only emits UVA light; the other only emits UVB light. User selects which handpiece to use from the touchscreen.	One handpiece that can emit either UVA or UVB light. The user selects which type from the touchscreen.
Camera	No camera.	Camera integrated into handpiece and displayed on tablet.
Keylock feature	Any light emission requires keylock to be turned to an ‘on’ position.	Any light emission requires keylock to be turned to an ‘on’ position.

Conclusions

Based on the test results, the similar indications for use, and the similar technological characteristics, the AURORA is considered to be substantially equivalent to the predicate device.