March 8, 2023

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

Re: K230076
Trade/Device Name: Enhanced AURORA™ system, and related accessories
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet Lamp For Dermatologic Disorders
Regulatory Class: Class II
Product Code: FTC, GEX
Dated: January 9, 2023
Received: January 10, 2023

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,

Jianting Wang -S

Jianting Wang
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

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)*
K230076

Device Name
Enhanced AURORA TM Medical Diode system, and related accessories

Indications for Use *(Describe)*
The Enhanced AURORA™ Medical Diode system and related accessories 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)

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
K230076

Psoria-Shield Inc's Enhanced AURORA™ Medical Diode System, and related accessories

The following information is provided as required by 21 C.F.R. § 807.87 (2003) for Psoria-Shield Inc's AURORA system Traditional 510(k) premarket notification:

Document Control Clerk,

Pursuant to 21 CFR 807.87, this is to notify you of the intention of Psoria-Shield, Inc. to introduce the Enhanced AURORA™ Medical Diode system and related accessories into commerce.

GENERAL INFORMATION:

Premarket Application Submitter:
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Email: jy@psoriashield.com

Date Prepared: January 9, 2023

Classification Name: Ultraviolet Lamp For Dermatologic Disorders
Laser surgical instrument for use in general and plastic surgery and in dermatology

CFR Citation Number: 21 CFR 878.4630
21 CFR 878.4810

Product Code: FTC, GEX

Classification:	Class II
Review Panel:	General & Plastic Surgery
Trade Name:	Enhanced AURORA™ Medical Diode system and related accessories
Common Name:	The Enhanced AURORA™ Medical Diode system and related accessories is a Diode medical device for dermatological disorders.
Generic Name:	AURORA™ system, and related accessories
Establishment Registration Number:	3008872264
Predicate Devices:	The Psoria-Shield, Inc. AURORA™ (K192411 July 2, 2020) The PhotoMedex, Inc. XTRAC Ultra^2 Excimer Laser System, Model AL10000 (K073659 January 2, 2008).
Purpose of this Submission:	Psoria-Shield is seeking to introduce the Enhanced AURORA ™ Medical Diode system and related accessories into commerce claiming substantial equivalence to the Psoria-Shield AURORA™ (K192411) and the PhotoMedex XTRAC Ultra^2 Excimer Laser System, Model AL10000 (K073659).
Indications for Use:	The Enhanced AURORA™ Medical Diode system and related accessories 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 Enhanced AURORA™ Medical Diode system and related accessories is designed to allow a clinician to easily apply UVA or UVB light to the patient's affected skin. The clinician selects the desired treatment type (UVA or UVB light) and applies the light through the appropriate handpiece by pointing the exit aperture towards the affected skin area. The device is comprised of four main components: - A base station - A touchscreen where the user can enter system commands - Two handpieces connected to the base by power cables. One handpiece contains diode emitters that, when activated, emit UVA light. The other handpiece emits UVB light. Either handpiece will only operate if the appropriate wavelength is selected, so a user cannot

accidentally activate the incorrect handpiece. Activation of energy occurs on depression of a trigger in the handpiece.

- A printer accessory that can print out verification of treatment parameters for hard copy records.

The technical specifications for the AURORA are as follows:

- Weight: 20 lbs
- Size: 19" (W) x 14" (L) x 8" (H)
- Min/Max power output (UVA): 100 mJ/cm^2 / 3400 J/cm^2
- Min/Max power output (UVB): 100 mJ/cm^2 / 3400 mJ/cm^2
- Power Increase Increments 20mJ/100mJ
- Size of beam: 2.88 cm^2
- Dosage Accuracy: 10%

Technical Characteristics: The Enhanced AURORA™ Medical Diode system and related accessories has the exact technological characteristics as the previously cleared AURORA™ (K192411 July 2,2020). Additionally, Psoria Shield is claiming substantial equivalence to the PhotoMedex XTRACT (K073659 January 2,2008).

The Enhanced AURORA™ Medical Diode system and related accessories emits either UVA or UVB light, depending on which has been selected by the clinician. The power output is the same between UVA or UVB. The treatment area is the same between UVA or UVB. Treatment instructions are the same between both the UVA and UVB. Thus, the modified AURORA is the same device as the cleared AURORA™ (K192411 July 2,2020) except for the modifications listed in table below, and for which Psoria-Shield is seeking clearance:

Modification	**Detailed description of modification**
A modification was implemented to improve the communication between the Enhanced AURORA and the thermal printer. Minor changes were made to the code of the Enhanced AURORA. These modified changes are incorporated in the new version of the code 1.2.4.	The update consisted of updating the USB Printer to improve the communication of the USB thermal printer address. The update was done to ensure that the firmware/software connection was fixed to allow the Enhanced AURORA™ Medical Diode system to properly function for the user. This was done to allow the clinician to utilize the thermal printer function while additionally preventing them from overriding the Patient ID function while utilizing the device. A software change to the code was made in order for the clinician to read results before printing and to include an added treatment area to the results screen on the Enhanced AURORA ™ Medical Diode system.

Performance Data:

Psoria-Shield has performed bench testing consistent with design verification activities required under 21 CFR 820 to confirm the design modifications have no effect on the safety or effectiveness of the modified device. This was confirmed through verifying that UVA and UVB energy dosage output are within 10% of user-selected power settings.

Testing was performed using a production-equivalent Enhanced AURORA™ Medical Diode system and related accessories, with energy dosage measured using a Coherent PowerMax PC thermopile sensor array. Testing was performed to confirm the joule output of the device in a cm^2 area in the center of both the thermopile and using the center of the chipset arrays for the most accurate reading possible. Screenshots of the AURORA device were taken at the same time to demonstrate the dosage that the device was calibrated to deliver in the pulse.

Substantial Equivalence:

The Enhanced AURORA™ Medical Diode system and related accessories has the exact same use as the previously cleared AURORA™ (K192411 July 2, 2020). In addition, the Enhanced AURORA™ Medical Diode system and related accessories has the exact indications and principles of operation as the predicate devices, the exact technological characteristics to the AURORA™ (K192411 July 2,2020) and very similar technical characteristics to the PhotoMedex XTRACT (K073659 January 2, 2008).

Although there are minor differences between the Enhanced AURORA™ Medical Diode system and related accessories and its predicate devices. Note that the indications for use (IFU's) are not being changed, modified, or altered in any fashion from the predicate devices. Thus, the Enhanced AURORA™ Medical Diode system and related accessories is substantially equivalent to the predicate devices.

Conclusion:

In summary, the company's Enhanced AURORA™ Medical Diode system and related accessories has the exact same use as the previously cleared AURORA™ (K192411 July 2,2020). In addition, the Enhanced AURORA™ Medical Diode system and related accessories has the exact indications and principles of operation as the predicate devices, and the exact technological characteristics to the AURORA™ (K192411 July 2,2020) and very similar technical characteristics to the PhotoMedex XTRACT (K073659 January 2, 2008). Although there are minor differences between the Enhanced AURORA™ Medical Diode system and related accessories and its predicate devices as summarized in table below. Note that the indications for use (IFU's) are not being changed, modified, or altered in any fashion from the predicate devices. Thus, the Enhanced

AURORA™ Medical Diode system and related accessories is substantially equivalent to the predicate devices.

Substantial Equivalence Table Comparing Subject and Predicate Device

	Psoria Shield Enhanced AURORA™ Medical Diode system and related accessories (K230076)	**Psoria Shield AURORA™ (K192411)**	**PhotoMedex XTRAC Ultra^2 Excimer Laser System, Model AL10000 (K073659)**
Intended Use	**The Enhanced AURORA™ and related accessories is intended to be used for the treatment of dermatologic disorders.**	**The AURORA is intended to be used for the treatment of dermatologic disorders.**	**The intended use is targeted UVB phototherapy for treatment of the skin conditions including psoriasis, vitiligo, atopic dermatitis, and leukoderma.**
Indications for Use	**The Enhanced AURORA™ Medical Diode system and related accessories 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 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.**	**UVB phototherapy for psoriasis, vitiligo, atopic dermatitis, and leukoderma.**
Wavelength	**UVA:350-395nm** **UVB:300-320nm**	**UVA: 350-395nm** **UVB:320-320nm**	**308nm**

Maximum Fluence to Tissue:	**Up to 3,400mJ/cm²**	**Up to 3,400mJ/cm²**	**2-3.8 mJ/cm2**
Pulse Duration:	**C/W**	**C/W**	**Quasi continuous output**
Beam Delivery:	**Flexbile Fiber Optic and Therapeutic Handpieces**	**Flexible Fiber Optic and Therapeutic Handpieces**	**Flexible Fiber Optic and Therapeutic Handpieces**
Aiming Beam	**YES**	**YES**	**YES**
Power Source	**110V wall power**	**110V wall power**	**110V wall power**
Dimensions	**H: 19** **D: 14** **W: 8**	**H:19** **D:14** **W: 8**	**H: 34** **D: 39** **W:18**
Safety Features	**Key lock to prevent accidental energy emission and Emergency stop button**	**Key lock to prevent accidental energy emission and Emergency stop button**	**Key lock to prevent accidental energy emission and emergency stop button**
Weight	**20lbs**	**20lbs**	**220lbs**
Accessories	**USB-connected printer**	**USB-connected printer**	**NA**