May 1, 2026

Choyang Medics Co., Ltd.
% Kim Kyung-Hwan
Representative Consultant, RA/QA
SMB Korea Co.
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Re: K254234
Trade/Device Name: Phototherapy System (DUV-COMBO)
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet Lamp For Dermatologic Disorders
Regulatory Class: Class II
Product Code: FTC
Dated: December 29, 2025
Received: December 29, 2025

Dear Kim Kyung-Hwan:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tanisha Hithe

Digitally signed by Tanisha Hithe
Date: 2026.05.01 13:28:13 -04'00'

Tanisha Hithe
Assistant Director
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254234

Device Name
Phototherapy System (DUV-COMBO)

Indications for Use *(Describe)*
The DUV-COMBO Phototherapy System is indicated for use in targeted PUVA photochemistry and UVB phototherapy to treat skin conditions such as psoriasis, vitiligo, atopic dermatitis (eczema), and seborrheic dermatitis. Additionally, its UVB channel is indicated for treating 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.

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510(k) Summary

K254234

Prepared in Accordance with 21 CFR 807.92

APPLICATION INFORMATION

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Date Prepared: April 29, 2026

I. DEVICE IDENTIFICATION

Trade or Proprietary Name:	Phototherapy System (DUV-COMBO)
Common or Usual Name:	Phototherapy System
Classification Name:	Ultraviolet lamp for dermatologic disorders (21 CFR 878.4630)
Regulatory Class:	Class II
Product Code:	FTC
Classification Panel:	General & Plastic Surgery

II. PREDICATE DEVICE

Device Name:	PSORIA-SHIELD AURORA (K192411)
Manufacturer:	Psoria-Shield.
Product Code:	FTC
Classification:	Class II (21 CFR 878.4630)

III. DEVICE DESCRIPTION

The DUV-COMBO is a professional-grade Phototherapy System utilizing LED technology to deliver controlled narrow-band ultraviolet radiation for dermatological treatment. The device emits UVA wavelengths between 360-390 nm with measured peak emission at 371.3 nm, and UVB wavelengths between 300-320 nm with measured peak emission at

308.8 nm.

The system comprises a main console housing digital control electronics and power management circuitry, two dedicated handpieces for separate delivery of UVA and UVB radiation, and six types of interchangeable handpiece covers designed to accommodate different anatomical treatment sites. A touchscreen interface enables clinicians to program treatment parameters including wavelength mode selection, irradiance intensity adjustment, and exposure time settings. Real-time sensors continuously monitor output characteristics to maintain accurate therapeutic dose delivery throughout each treatment session.

IV. INDICATION FOR USE

The DUV-COMBO Phototherapy System is indicated for use in targeted PUVA photochemistry and UVB phototherapy to treat skin conditions such as psoriasis, vitiligo, atopic dermatitis (eczema), and seborrheic dermatitis. Additionally, its UVB channel is indicated for treating leukoderma.

V. TECHNOLOGICAL CHARACTERISTICS COMPARISON

	SUBJECT Device	**PRIMARY PREDICATE Device (K192411)**	**Significant Difference**
Manufacturer	Choyang Medics Co., Ltd.	Psoria-Shield Inc.	–
Trade Name	DUV-COMBO	Psoria-Shield AURORA	–
Regulation Description	Ultraviolet lamp for dermatologic disorders	Ultraviolet lamp for dermatologic disorders	–
Regulation Number	878.4630	878.4630	No difference
Product Code	FTC	FTC	No difference
Class	2	2	No difference
Intended Use/ Indications for Use	The DUV-COMBO Phototherapy System is indicated for use in targeted PUVA photochemistry and UVB phototherapy to treat skin conditions such as psoriasis, vitiligo, atopic dermatitis (eczema), and seborrheic dermatitis. Additionally, its UVB channel is indicated for treating leukoderma.	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.	No difference
Components	Base station Touchscreen/GUI Two handpieces	Base station Touchscreen/GUI Two handpieces	No difference
Operating System	Windows CE 6.0	Linux Ubuntu	Difference
Safety Features	Key lock to prevent accidental energy emission.	Key lock to prevent accidental energy emission.	No difference
Power Source	100 – 240V	110V wall power	Difference
Dimensions (inch)	19 W × 15” L × 38” H	19” W × 14” L × 8” H	Difference
Weight (lbs)	46	12	Difference

	SUBJECT Device	PRIMARY PREDICATE Device (K192411)	Significant Difference
Accessories	Handpiece Protective Cap; LED UV Cover	USB-connected printer	Difference
Available Wavelengths (nm)	UVA: 360 to 390, peak 371.3 nm UVB: 300 to 320, peak 308.8 nm	UVA: 350 to 395 UVB: 300 to 320	Difference
Minimum Energy Density (UVA) (J/cm^2)[1)]	0.1	0.1	No difference
Maximum Power (UVA) (J/cm^2)	3.4	3.4	No difference
Minimum Energy Density (UVB) (J/cm^2)	0.05	0.1	Difference
Maximum Energy Density (UVB) (J/cm^2)	3.4	3.4	No difference
Treatment Area (cm^2)	UVA: 1.7 / 7.0 / 11.8 / 15.8 / 20.0 / 30.0 / 42.0 UVB: 1.7 / 7.0 / 11.8 / 15.8 / 20.0 / 30.0 / 42.0	2.88	Difference
Handpiece design	Two handpieces. One handpiece emits UVA light only; the other emits UVB light only. The user selects which handpiece to use from the touch screen.	Two handpieces. One handpiece only emits UVA light; the other only emits UVB light. User selects which handpiece to use from the touchscreen.	No difference
Keylock feature	Any light emission requires the keylock to be in the "on" position.	Any light emission requires keylock to be turned to an ‘on’ position.	No difference

The DUV-COMBO shares fundamental technological characteristics with the predicate device Psoria-Shield AURORA while incorporating certain design differences that do not affect safety, effectiveness, or raise new questions of safety and effectiveness.

Similarities:

Both devices utilize LED light source technology to generate narrow-band ultraviolet radiation for dermatological phototherapy. Both feature dual-channel architecture providing separate handpieces for UVA and UVB treatment delivery. Both employ digital touchscreen interfaces for treatment parameter control and both incorporate keylock safety mechanisms to prevent unauthorized device activation. Both utilize biocompatible materials for patient-contacting components and both are intended for professional healthcare facility use.

Differences:

The devices differ in certain non-critical technological aspects. The DUV-COMBO utilizes Windows CE 6.0 operating system for internal control software while the predicate employs Linux Ubuntu. The DUV-COMBO has physical dimensions of 19 inches × 15 inches × 38 inches with weight of 46 pounds compared to predicate dimensions of 19 inches × 14 inches × 8 inches and weight of 12 pounds. The DUV-COMBO provides treatment areas

of 1.7, 7.0, 11.8, 15.8, 20.0, 30.0, and 42.0 cm^2 (UVA and UVB), compared to 2.88 cm^2 for the primary predicate device (K192411). The reference device K181805 (UV Phototherapy, Xuzhou Kernel Medical Equipment Co., LTD.) has similar indications for use and technical characteristics, and provides treatment areas such as 60 cm^2, 100 cm^2, and 104 cm^2, confirming that larger treatment areas are within the established performance range of legally marketed equivalent devices, and that the DUV-COMBO treatment area differences do not raise new questions of safety or effectiveness. The DUV-COMBO maximum dose outputs are 3.4 J/cm^2 for both UVA and UVB channels, identical to the 3.4 J/cm^2 maximum of the predicate device. These specifications have been verified by performance testing, confirming compliance with the stated dosage range.

VI. PERFORMANCE DATA

1. Non-Clinical Testing

Substantial equivalence determination is based on comprehensive nonclinical testing. Clinical studies were not required.

Electrical, Mechanical, and Thermal Safety:

Testing was conducted per IEC 60601-1:2005/AMD1:2012/ISH1:2021(Amendment), "Interpretation Sheet 1 – Amendment 1 - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance" for general requirements, 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, cosmetic and aesthetic use" for particular requirements for UV light source equipment, and IEC 60601-1-6:2010/AMD2:2020(Amendment), "Amendment 2 – Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability" for usability engineering. Results confirmed full compliance with requirements for basic safety, essential performance, mechanical strength, thermal stability, and human factors.

Electromagnetic Compatibility:

Testing was performed per IEC 60601-1-2:2014+AMD1:2020 Edition 4.1, "Amendment 1 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests" for professional healthcare facility environments, CISPR 11:2016+AMD2:2019, "Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement" for radiofrequency emissions, and IEC 61000 series standards for immunity testing. Results confirmed device maintains essential performance under electromagnetic disturbances including electrostatic discharge, radiated and conducted radiofrequency electromagnetic fields,

electrical fast transients and bursts, surge, power frequency magnetic fields, voltage dips and interruptions, and proximity fields from wireless communication devices.

Photobiological Safety:
Testing was conducted per IEC 62471:2006, "Photobiological safety of lamps and lamp systems" to evaluate photobiological safety of UV emission sources. Results confirmed ultraviolet radiation emission levels are within acceptable safety limits for intended dermatological treatment applications.

Biocompatibility:
Assessment was performed per ISO 10993-1:2018, "Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process" for medical devices. Testing confirmed patient-contacting handpiece cover materials composed of ethylene propylene copolymer are suitable for limited duration skin contact applications without adverse biocompatibility effects.

Performance Verification:
Functional testing validated UV wavelength accuracy for UVA (360-390 nm) and UVB (300-320 nm) emission ranges, irradiance output accuracy and reproducibility at specified distances, dose calculation precision across operating ranges, and treatment timing accuracy. All performance parameters passed the required criteria, as documented in Test Report.

Software Verification and Validation:
Testing was completed per FDA Guidance: "Content of Premarket Submissions for Device Software Functions – Guidance for Industry and Food and Drug Administration Stuff" (published June 2023), and IEC 62304:2015, "Medical device software - Software life cycle processes" requirements for medical device software lifecycle processes. Comprehensive verification and validation activities including unit testing, integration testing, system testing, and regression testing confirmed software safety, reliability, and proper implementation of safety-critical functions.

These nonclinical testing results support substantial equivalence determination by demonstrating the DUV-COMBO meets applicable international safety and performance standards, delivers therapeutic ultraviolet radiation within clinically effective wavelength and dose parameters equivalent to the predicate device, and incorporates safety mechanisms and controls comparable to those of the legally marketed predicate device.

VII. CONCLUSIONS

Based on comprehensive nonclinical testing, the DUV-COMBO Phototherapy System is as safe, as effective, and performs as well as the predicate device Psoria-Shield AURORA (K192411).

Therefore, the DUV-COMBO Phototherapy System is substantially equivalent to the legally marketed predicate device.