March 13, 2025

Boston Aesthetics INC
Cao Hongmei
General Manager
1521 Concord Pike Suite 201
Wilmington, Delaware 19803

Re: K244022
Trade/Device Name: 308nm UV Phototherapy System (UV-K); 308nm UV Phototherapy System (UV-X); 308nm UV Phototherapy System (UV-Y); 308nm UV Phototherapy System (UV-Z)
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet Lamp For Dermatologic Disorders
Regulatory Class: Class II
Product Code: FTC
Dated: December 26, 2024
Received: December 27, 2024

Dear Cao Hongmei:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

YAN FU -S Digitally signed by YAN FU -S
Date: 2025.03.13 19:17:31 -04'00'

for 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

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)*
K244022

Device Name
308nm UV Phototherapy System (UV-K); 308nm UV Phototherapy System (UV-X); 308nm UV Phototherapy System (UV-Y); 308nm UV Phototherapy System (UV-Z)

Indications for Use *(Describe)*
The 308nm UV Phototherapy System is intended to be used for the treatment of psoriasis, vitiligo, seborrheic dermatitis, atopic dermatitis, and leukoderma. It is used on intact skin only.

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
PRAStaff@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."

K244022 - 510(k) Summary

This summary of 510(K) safety and effectiveness information is submitted As Required by requirements of SMDA and 21 CFR §807.92.

1. Administrative Information

Submission Date

December 26, 2024

Submission Correspondent

Name: Boston Aesthetics INC

Address: 1521 Concord Pike Suite 201 Wilmington DE 19803

Tel: +001 949-792-8168

E-mail: bsnaesthetics@gmail.com

Contact: Ms. Hongmei Cao

2. Device Information

Type of 510(k) Submission:	Traditional
Device Name:	308nm UV Phototherapy System
Model:	UV-K; UV-X; UV-Y; UV-Z
Device Classification:	Light, Ultraviolet, Dermatological
Regulation Description:	Ultraviolet lamp for dermatologic disorders
Regulation Medical Specialty:	General & Plastic Surgery
Regulation Number:	878.4630
Product Code:	FTC
Device Class:	2

3. Predicate Device

510(K) Number:	K172273
Device name:	308nm Excimer System
Device model:	XECL-308C
Manufacturer:	Chongqing Peninsula Medical Technology Co., Ltd.
Classification Name:	Ultraviolet lamp for dermatologic disorders
Regulation Medical Specialty:	General&Plastic Surgery
Product code:	FTC
Regulation number:	878.4630

4. Reference Device

Items	Reference 1	Reference 2
510(K) Number:	K170489	K191571
Manufacturer:	Clarify Medical, Inc.	Xuzhou Yongkang Electronic Science Technology Co., Ltd
Device name:	Clarify Phototherapy System	UV Radiation Treatment System
Model:	N/A	YK-6000B
Classification Name:	Ultraviolet lamp for dermatologic disorders	
Regulation Medical Specialty:	General&Plastic Surgery	
Product code:	FTC	
Regulation number:	878.4630	

5. Device Description

The 308nm UV Phototherapy System is available in four models, UV-K , UV-Y, UV-Y and UV-Z. It is a portable medical device, which consists of LED light board, heat dissipation module, control circuit, drive circuit, battery (applicable to UV-X, UV-Z), and power adapter. It is a therapeutic product under the direction of a physician for individuals who require ultraviolet radiation for diagnosed skin disorders, which can be used in hospital, clinics and households.

The device is mainly composed of a host and a power adapter. The LED light board of the device host contains light emitting diodes (LEDs), which create narrowband UVB light centered at a wavelength 308nm(±2nm) for the purpose of phototherapy. They are intended to be use in localized phototherapeutic treatment of dermatologic conditions(excluding eyes), such as psoriasis, vitiligo, seborrheic dermatitis, atopic dermatitis, and leukoderma. It is for the partial treatment and is intended to be used on intact skin only.

The materials of the parts of the 308nm UV Phototherapy System that come into contact with the human body are mainly: PC, ABS.

5. Indication for Use

The 308nm UV Phototherapy System is intended to be used for the treatment of psoriasis, vitiligo, seborrheic dermatitis, atopic dermatitis, and leukoderma. It is used on intact skin only.

6. Comparison with predicate device

A comparison of the intended use and technological characteristics of the subject device and predicate device is provided in the table below:

Items	Subject Device (K######)	Predicate Device (K172273)	Reference Device (K170489)	Reference Device (K191571)	Comparison
Device name	308nm UV Phototherapy System	308nm Excimer System	Clarify Medical Phototherapy System	UV Radiation Treatment System	/
Device model	UV-K, UV-X, UV-Y, UV-Z	XECL-308E	N/A	YK-6000A	/
Device picture					/
Type of Use	Prescription Use	Prescription Use	Prescription Use	Prescription Use	Same
Use environment	Hospitals, clinics and households	Hospitals, clinics and households	Home / Physician's office	Hospitals, clinics and households	Same
Indications for use	The 308nm UV Phototherapy System is intended to be used for the treatment of psoriasis, vitiligo, seborrheic dermatitis, atopic dermatitis, and leukoderma. It is used on intact skin only.	The 308nm Excimer System is intended to be used for the treatment of psoriasis and vitiligo. It is to be used on intact skin only.	The Clarify Medical Phototherapy System is an Ultraviolet Light Emitting Medical Device. It is intended for use in localized phototheraputic treatment of dermatologic conditions such as psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis and lenkoderma on all skintypes (I-VI).	The UV Radiation Treatment System models YK-6000A, YK-6000A-T, YK-6000B, and YK-6000B-T, are intended for use under the direction of a physician, for the treatment of vitiligo, psoriasis, and eczema. The devices are intended for treatment of these conditions on Fitzpatrick Skin Types (I-VI).	Similar & Comparable
Mode of operation	Handheld	Handheld	Handheld	Handheld	Same
Re-usable	Yes	Yes	Yes	Yes	Same
Light source	LED UV lamps	Xenon-Chlorine (XeCl) excimer lamp	LED UV lamps	LED UV lamps	Same
UV spectral	UVB	UVB	UVB	UVA&UVB	Same
UV light wavelength	308nm±2nm	308nm±2nm	300nm-320nm	UVA: 320nm~400nm UVB: 300nm~320nm	Same
Max Power Output	UV-K&UV-X: 30 mW/cm^2 UV-Y&UV-Z: 50 mW/cm^2	50mW/cm^2	3-15mW/cm2	10mW/cm^2	Comparable

Items	Subject Device (K######)	Predicate Device (K172273)	Reference Device (K170489)	Reference Device (K191571)	Comparison
Maximum treatment dose	≤ 5J/cm2	2J/cm2	Not Publicly Available	Not Publicly Available	Comparable
Action area	Partial treatment excluding eyes	Partial treatment excluding eyes	Not Publicly Available	Partial treatment excluding eyes	Same
Treatment area	3cm^2 ~ 3.41cm^2	16cm^2	4.5cm^2	Max 15cm^2	Comparable
Treatment time	UV-K&UV-X: 1~140s UV-Y&UV-Z: 1~100s	1~40s	Not Publicly Available	5~20 min	Comparable
Display Type	OLED	Not Publicly Available	Not Publicly Available	LED	Same
User Interface	Hardware interface	Hardware interface	Touch screen on mobile device and start button on host body	Hardware interface	Same
Power source	UV-K & UV-Y: Adapter UV-X & UV-Z: Adapter + lithium battery	Adapter	Rechargeable battery	AC outlet	Same
Operating environment	Ambient temperature: 5℃~35℃ Relative humidity: ≤ 80% Atmospheric pressure: 780hPa~1060hPa	Ambient temperature: 15℃~35℃ Relative humidity: ≤ 80% Atmospheric pressure: 860hPa~1060hPa	Not Publicly Available	Not Publicly Available	Comparable
Transport/Storage environment	Ambient temperature: -20℃~50℃ Relative humidity: ≤ 93% Atmospheric pressure: 700hPa ~1060hPa	Ambient temperature: -20℃～45℃ Relative humidity: 10-85%RH Atmospheric pressure: 500hPa~1060hPa	Not Publicly Available	Not Publicly Available	Comparable
Safety & Performance	IEC60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 62471 IEC 60601-2-57 IEC 60601-2-83	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57 IEC 62471	IEC60601-1 IEC 60601-1-2 IEC 60601-1-4 IEC 60601-2-57 IEC 62471	IEC60601-1 IEC 60601-1-2 IEC 60601-2-57 IEC 62471	Same
Patient-Contact material	ABS; PC	ABS; PC	ABS	ABS	Same

The subject device and the predicate device have the same intended use. Although the subject device and the predicate device have several different technological characteristics as noted in the table above, the differences do not raise different questions of safety and effectiveness. Therefore, we consider that the subject device is as safe and effective as the predicate device.

7. Summary of Non-Clinical performance Testing

7.1. Electromagnetic Compatibility and Electrical Safety Test

The subject device has passed safety testing in according to following standards.

1) AAMI/IEC 60601-1:2005/(R)2012 and A1:2012,C1:2019/(R)2012 and A2:2010/(R)2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
2) ANSI AAMI 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.
3) IEC 60601-1-11 Edition 2.0 2015-01 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.
4) IEC 60601-2-57 Edition 1.0 2011-01 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
5) IEC 60601-2-83 Edition 1.0 2019-05 Medical electrical equipment -Part 2-83: Particular requirementsfor the basic safety and essential performance of home lighttherapy equipment
6) IEC 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems

7.2. Biocompatibility Test

Biocompatibility testing was conducted in accordance with the 2020 FDA guidance “Use of International Standard ISO 10993, Biological Evaluation of Medical Device Part 1: Evaluation and Testing.”
The testing includes:

1) Cytotoxicity per ISO 10993-5: 2009 Biological evaluation of medical devices - Part 5: Tests for in vitro Cytotoxicity.
2) Sensitization per ISO 10993-10: 2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
3) Irritation per ISO 10993-23: 2021 Biological evaluation of medical devices - Part 23: Tests for irritation

The user- contacting materials were shown to be non-cytotoxic, non-irritating and non-sensitizing.

7.3. Software

Software documentation of the subject device was provided in accordance with the FDA guidance Document- “*Content of Premarket Submissions for Device Software Functions: Guidance for Industry and Food and Drug Administration Staff*”, which was issued in 06/14/2023 to support a device’s Basic Documentation Level.

8. Conclusion

The subject device and the predicate device have the same intended use and any difference in the technological characteristics does not raise any new issues or concerns of safety or effectiveness. The results of the testing described above demonstrate that the subject device is as safe and effective as the predicate device (K172273) and supports a determination of substantial equivalence.