December 19, 2024

Shenzhen Nuon Medical Equipment Co., Ltd
Alain Dijkstra
CEO
1st Floor-3rd Floor, No. 27-2, Xintang Rd, Xintian Community
Fuhai Street, Baoan District
Shenzhen, Guangdong 518000
China

Re: K242700
Trade/Device Name: Radiant Renewal Skincare Lid (HD-59A, HD-59B, HD-59D, HD-70, HD-72, HD-72A, HD-73A, HD-73B, HD-116, HD-116A, HD-53A, HD-53B)
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OHS, OLP
Dated: September 4, 2024
Received: September 9, 2024

Dear Alain Dijkstra:

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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2024.12.19 12:21:50 -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

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)*
K242700

Device Name
Radiant Renewal Skincare Lid (Model: HD-59A, HD-59B, HD-72, HD-73A, HD-116, HD-53A, HD-70, HD-59D, HD-72A, HD-73B,HD-116A,HD-53B)

Indications for Use *(Describe)*
The Radiant Renewal Skincare Lid (Model: HD-59A, HD-59B, HD-72, HD-73A, HD-116, HD-53A) is intended for the treatment of wrinkles for over-the-counter cosmetic use.

The Radiant Renewal Skincare Lid (Model: HD-70) is intended for the treatment of wrinkles and the mild to moderate inflammatory acne for over-the-counter cosmetic use.

The Radiant Renewal Skincare Lid (Model: HD-59D, HD-72A, HD-73B,HD-116A,HD-53B) is intended for the treatment of the mild to moderate inflammatory acne for over-the-counter cosmetic use.

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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K242700 - 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

Sponsor Name: Shenzhen Nuon Medical Equipment Co., Ltd
Establishment Registration Number: 3030541658
Address: 1st Floor-3rd Floor, No. 27-2, Xintang Road, Xintian Community, Fuhai Street, Baoan District, Shenzhen,Guangdong China
Contact Person (including title): Alain Dijkstra (CEO)
Tel: +86-0755-82129361
Fax: +86-755-25024651
E-mail: alaindijkstra@nuonmedical.com

Application Correspondent:

Contact Person: Alain Dijkstra
Company: Shenzhen Nuon Medical Equipment Co., Ltd
Address:1st Floor-3rd Floor, No. 27-2, Xintang Road, Xintian Community, Fuhai Street, Baoan District, Shenzhen,Guangdong China
Tel:+86-0755-82129361
Fax: +86 755 25024651
Email: alaindijkstra@nuonmedical.com

2. Subject Device Information:

Trade Name:Radiant Renewal Skincare Lid (Models:HD-59A, HD-59B, HD-59D, HD-70, HD-72, HD-72A, HD-73A, HD-73B, HD-116, HD-116A, HD-53A, HD-53B)
Classification Name: Light Based Over The Counter Wrinkle Reduction; Over-The-Counter Powered Light Based Laser For Acne
Review Panel: General & Plastic Surgery
Product Code: OHS, OLP
Regulation Number:21 CFR 878.4810
Regulation Class: II

3. Predicate Device Information

Predicate Device 1 (K230293)

Sponsor: THERABODY, Inc.
Trade Name: TheraFace Mask
Classification Name: Light Based Over the Counter Wrinkle Reduction
Review Panel: General & Plastic Surgery
Product Code: OHS
Regulation Number: 21 CFR 878.4810
Regulation Class: II

Predicate Device 2 (K240089)
Sponsor: Shenzhen Kaiyan Medical Equipment Co., Ltd
Trade Name: Face Patches(MT-12MA, MT-12MC)
Classification Name: Light Based Over the Counter Wrinkle Reduction；Over-The-Counter Powered Light Based Laser For Acne
Review Panel: General & Plastic Surgery
Product Code: OHS, OLP, GEX
Regulation Number: 21 CFR 878.4810
Regulation Class: II

Predicate Device 3 (K241718)
Sponsor: Shenzhen Aozemei Technology Co. Ltd
Trade Name: Micro-current Facial Beauty Device(AM-810B, AM-810W, AM-812B, AM-812W)
Classification Name: Light Based Over the Counter Wrinkle Reduction; Over-The-Counter Powered Light Based Laser For Acne
Review Panel: General & Plastic Surgery
Product Code: OHS,OLP
Regulation Number: 21 CFR 878.4810
Regulation Class: II

Predicate Device 4 (K241857)
Sponsor: Dongguan Boyuan Intelligent Technology Co., Ltd.
Trade Name: LED Light Therapy Device (KFB290, KFB291, KFB265, KFB293)
Classification Name: Light Based Over the Counter Wrinkle Reduction; Over-The-Counter Powered Light Based Laser For Acne; Lamp, infrared, therapeutic heating
Review Panel: General & Plastic Surgery
Product Code: OHS, OLP, ILY
Regulation Number: 21 CFR 878.4810
Regulation Class: II

Predicate Device 5 (K203271)
Sponsor: Shenzhen Kaiyan Medical Equipment Co., Ltd
Trade Name: Aduro Light Therapy Handheld (Model: HD-03A,HD-25A,HD-07A)
Classification Name: Light Based Over the Counter Wrinkle Reduction; Over-The-Counter Powered Light Based Laser For Acne
Review Panel: General & Plastic Surgery
Product Code: OHS, OLP
Regulation Number: 21 CFR 878.4810
Regulation Class: II

Predicate Device 6 (K241293)
Sponsor: YASSEN WELLNESS LLC
Trade Name: LED Light Therapy Device, ELIXIR MD™
Classification Name: Powered Laser Surgical Instrument
Review Panel: General & Plastic Surgery
Product Code: GEX
Regulation Number: 21 CFR 878.4810
Regulation Class: II

4. Device Description

The Radiant Renewal Skincare Lid (Model: HD-59A, HD-59B, HD-59D, HD-70, HD-72, HD-72A, HD-73A, HD-73B, HD-116, HD-116A, HD-53A, HD-53B) is a hand-held, rechargeable device powered by a lithium-Ion battery, designed for single-patient use. It offers wrinkle reduction through the emission of red light (wavelength: 630nm±10nm) and infrared light (wavelength: 830nm±10nm) and yellow light (wavelength: 630nm±10nm), and acne treatment through the emission of blue light(wavelength: 415nm±10nm).

There are 12 models of the device, each with similar core functionalities, but differing in the specific light treatments and additional features they offer.

Model HD-59A offers red and infrared light for wrinkle treatment, model HD-59B provides yellow light for wrinkle treatment, and model HD-59D uses blue light for acne treatment. These three models differ only in the light treatments they offer.

Model HD-70 features three treatment modes: mode 1 : Red light and infrared light for wrinkle reduction; mode 2: Yellow light for wrinkle reduction; mode 3: Blue light for acne treatment.

Models HD-72, HD-73A, and HD-116 offer two treatment modes: mode 1: Red light for wrinkle reduction; mode 2: Yellow light for wrinkle reduction;

Models HD-72A, HD-73B, and HD-116A provide only blue light for acne treatment.

The difference between HD-72 and HD-72A, HD-73A and HD-73B, and HD-116 and HD-116A lies in the light treatments they offer. Apart from this, the HD-72 series, HD-73A series, and HD-116 series differ only in appearance.

Model HD-53A offers only red light for wrinkle treatment while model HD-53B provides only blue light for acne treatment.

The package includes the main unit, a charging cable, a user manual, a tray and a cosmetic container(only for model HD-70). An optional squeeze tube is also available but not included by default. Except for model HD-70, which features an additional rotating rock button, other models are equipped with a single button to turn the device on or off and switch treatment modes. The device can also be used with other skincare products such as face creams, eye creams, serums, etc.

The device will automatically shut down after the recommended duration of 2 minutes. If you wish to continue the treatment, simply press the button to turn the device back on.

5. Intended Use / Indications for Use

The Radiant Renewal Skincare Lid (Model: HD-59A, HD-59B, HD-72, HD-73A, HD-116, HD-53A) is intended for the treatment of wrinkles for over-the-counter cosmetic use.

The Radiant Renewal Skincare Lid (Model: HD-70) is intended for the treatment of wrinkles and the mild to moderate inflammatory acne for over-the-counter cosmetic use.

The Radiant Renewal Skincare Lid (Model: HD-59D, HD-72A, HD-73B, HD-116A, HD-53B) is intended for the treatment of the mild to moderate inflammatory acne for over-the-counter cosmetic use.

6. Comparison to predicate devices

Compare with the predicate devices, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. The differences between the subject device and predicate devices do not raise new questions of safety or effectiveness.

Elements of Comparison	Subject device (K242700)	Predicate device 1 (K230293)	Predicate device 2 (K240089)	Predicate device 3 (K241718)	Predicate device 4 (K241857)	Predicate device 5 (K203271)	Predicate device 6 (K241293)	Remark
Manufacturer	Shenzhen Nuon Medical Equipment Co., Ltd	THERABODY, Inc.	Shenzhen Kaiyan Medical Equipment Co., Ltd	Shenzhen Aozemei Technology Co. Ltd	Dongguan Boyuan Intelligent Technology Co., Ltd.	Shenzhen Kaiyan Medical Equipment Co., Ltd	YASSEN WELLNESS LLC	--
510 (K) Number	K242700	K230293	K240089	K241718	K241857	K203271	K241293	--
Device Name	Radiant Renewal Skincare Lid (Model: HD-59A, HD-59B, HD-59D, HD-70, HD-72, HD-72A, HD-73A, HD-73B, HD-116, HD-116A, HD-53A, HD-53B)	TheraFace Mask	Face Patches(MT-12MA, MT-12MC)	Micro-current Facial Beauty Device (AM-810B, AM-810W, AM-812B, AM-812W)	LED Light Therapy Device (KFB290, KFB291, KFB265, KFB293)	Aduro light therapy Handheld(Model:HD-03A,HD-25A,HD-07A)	LED Light Therapy Device, ELIXIR MD™	--
Regulation Class	Class II	Class II	Class II	Class II	Class II	Class II	Class II	Same
Product Code	OHS,OLP	OHS	OHS, OLP, GEX	OHS, OLP	OHS, OLP,ILY	OHS, OLP	GEX	Same
Intended Location Use	Face	Face	Face	Face	Face	Face	Face	Same
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same

Indications for Use / Intended use	The Radiant Renewal Skincare Lid (Model: HD-59A, HD-59B, HD-72, HD-73A, HD-116, HD-53A) is intended for the treatment of wrinkles for over-the-counter cosmetic use. The Radiant Renewal Skincare Lid (Model: HD-70) is intended for the treatment of wrinkles and the mild to moderate inflammatory acne for over-the-counter cosmetic use. The Radiant Renewal Skincare Lid (Model: HD-59D, HD-72A, HD-73B, HD-116A,HD-53B) is intended for the treatment of the mild to moderate inflammatory acne for over-the-counter cosmetic use.	Red Light is intended to treat full face wrinkles Blue Light is intended to treat mild to moderate inflammatory acne Red + Infrared Light is intended to treat full face wrinkles	Face Patches (Model: MT-12MA) is an Over-the-Counter (OTC) device intended for treatment of mild to moderate inflammatory acne. Face Patches (Model: MT-12MC) is an Over-the-Counter (OTC) device intended for treatment of mild to moderate inflammatory acne and full-face wrinkles (including periorbital wrinkles).	Micro-current Facial Beauty Device is intended for the treatment of facial wrinkles, and mild to moderate inflammatory acne.	KFB290, KFB291: Red light: Treatment of full-face wrinkles. Infrared light: Provide topical heating for the purpose of elevating tissue temperature; arthritis and muscle spasm;relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. Red+Infrared Light: Treatment of full-face wrinkles. Amber light: Treatment of full-face wrinkles. Blue light: Treatment of mild to moderate inflammatory acne. Mixed light(Red+Blue +Infrared): Treatment of mild to moderate inflammatory acne. KFB265, KFB293Red+Infrared Light: Treatment of wrinkles. Blue light: Treatment of mild to moderate inflammatory acne. Amber light: Treatment of wrinkles.	The Aduro light therapy Handheld (Model: HD-03A,HD-25A,HD-07A), the red light is intended for the treatment of periorbital wrinkles, and the blue light is intended for the treatment of the mild to moderate inflammatory acne.	ELIXIR MDTM use of the red, blue, Yellow and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions. The red light (633±10nm wavelength) is generally indicated to treatment of superficial, benign vascular, and pigmented lesions. The blue light (417±10 nm wavelength); is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. The Yellow light (590±10nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated for treatment of periorbital wrinkles and rhytides. The infrared light (835±15nm wavelength) is generally use for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.	Same
Housing Materials of Main Unit	PC & PP & Stainless Steel & ABS & Silicon& Aluminum&Silicone	ABS and PC	Silicone	ABS and PC	Unknown	ABS Plastic	Unknown	Similar, note1

Power Source	Lithium battery: For models HD-59A, HD-59B,HD-59D,HD-72, HD-72A,HD-73A, HD-73B,HD-116,HD-116A, HD-53A,HD-53B: 3.7V, 55mAh, 0.204Wh For model HD-70: 3.7V, 95mAh, 0.3515Wh	5-15V DC 2.5A max powered by 2 Li-Ion Batteries 3.7V 1500mAh	Lithium battery:3.6V, 65mAh, 0.234Wh	Adapter input: 5V 0.5A Internal battery: 3.7V/600mAh	Input: 100 -240 V, 50/60 Hz Output: 5V, 1A Lithium ion battery: 1300mAh	For HD-03A: 2600mAh, 3.7V Li battery; For HD-25A: 2600mAh, 3.7V Li battery; For HD-07A: 160mAh, 3.7V Li battery	AC 100-240 50/60Hz	Different, note 2
Sterility	Not applicable – this device is not sold sterile	Not applicable – this device is not sold sterile	Not applicable – this device is not sold sterile	Not applicable – this device is not sold sterile	Not applicable – this device is not sold sterile	Not applicable – this device is not sold sterile	Not applicable – this device is not sold sterile	Same
Type of Energy	LED	LED	LED	LED	LED	LED	LED	Same
LED wavelength	HD-59A: Red+IR 630±10nm&830±10nm HD-59B:Yellow 590±10nm HD-59D: Blue 415±10nm HD-70: Red+IR light mode 630±10nm&830±10nm Yellow light mode: 590±10nm Blue light mode: 415±10nm HD-72: Red light mode: 630±10nm Yellow light mode: 590±10nm HD-72A: Blue 415±10nm HD-73A: Red light mode: 630±10nm	Red: 633 ±10nm Blue: 415 ±10nm Red+IR:633nm±10nm/ 830 ± 10nm	MT-12MA: Red: 630 ± 10nm Blue: 415 ± 10nm MT-12MC: Infrared:830 ± 10nm Red: 630 ± 10nm Yellow:590± 10nm Blue: 415 ± 10nm	Blue: 415±10nm Amber: 605±10nm Red: 630±10nm	Red: 630~640nm IR: 845~855nm Blue: 460~470nm Amber: 600~610nm	Blue: 415 ± 10nm, Red: 630 ± 10nm	RBY irradiator: Red: 633 ± 10nm, Blue: 417± 10nm, Yellow: 590±10nm RBI irradiator: Red 633 ±10nm Blue 417 ± 10nm IR 835 ± 15nm	Same

	Yellow light mode: 590±10nm HD-73B: Blue 415±10nm HD-116: Red light mode: 630±10nm Yellow light mode: 590±10nm HD-116A: Blue 415±10nm HD-53A: Red 630±10nm HD-53B: Blue 415±10nm							
Irradiance (mW/cm^2)	HD-59A:Red+IR 630±10nm: 45~65 830±10nm: 30~50 Total:75~115 HD-59B: Yellow 590±10nm:10~30 HD-59D: Blue 415±10nm: 35~50 HD-70: Red+IR light mode: Red 630±10nm: 45~65 IR 830±10nm: 30~50 Total:75~115 Yellow light mode: 590±10nm:10~30 Blue light mode: 415±10nm: 35~50	Red light mode: 633±10nm: 73±5 Blue light mode: 415±10nm: 64±5 Red+IR light mode: Red 633±10nm: 73±5 IR 830±10nm: 55±5 Total: 128±5	For MT-12MA: 630nm: 5 415nm: 25 630+415nm: 30 For MT-12MC:630nm (type 1): 5 415nm: 25 Mode 1 - total: 30 830nm: 15 630nm (type 2): 20 Mode 2 - total: 35 Mode 3 - 590nm: 35	Amber light mode: 605±10nm：15 Red light mode: 630±10nm：2.5 Blue light mode: 415±10nm：1.4	Red light mode : 25 IR light mode:3 Red+IR mode: 30 Blue mode: 18 Amber mode: 20 Mix light mode: 9	Blue light mode: 415nm: 20~65 Red light mode: 630nm: 40~80	Red: 20～96 Blue: 10~120 Yellow(590±10nm): 5~35 IR: ≤ 70 Red/IR: 166 Blue/IR: 190	Different, note 3

	HD-72 Red light mode: 630±10nm: 15~40 Yellow light mode: 590±10nm: 8~30 HD-72A: Blue 415±10nm: 35~50 HD-73A Red light mode: 630±10nm: 15~40 Yellow light mode: 590±10nm: 8~30 HD-73B: Blue 415±10nm: 35~50 HD-116 Red light mode: 630±10nm: 15~40 Yellow light mode: 590±10nm: 8~30 HD-116A: Blue 415±10nm: 35~50 HD-53A: Red 630±10nm: 20~40 HD-53B: Blue 415±10nm: 35~50							

Treatment time	2 minutes per treatment	LED: 3 minutes each light mode for a total of 9 minutes per treatment, recommended to use 2 to 5 times per week	For MT-12MA (630+415nm): 3 minutes per treatment For MT-12MC (mode 1-630+415nm): 3 minutes per treatment For MT-12MC(mode 2 630+830nm): 9 minutes per treatment For MT-12MC(mode 3 590nm):21 minutes per treatment	Unknown	For red, blue and red+infrared: 10, 20, 30 minutes For infrared, amber light and mixed light: 10, 20 minutes.	3 minutes per treatment	20min (Recommended treatment time)	Different, note 2
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Same
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	IEC60601-1-2	IEC60601-1-2	IEC60601-1-2	IEC60601-1-2	Same
Safety	Compliant with IEC 60601- 1, IEC 60601-1-11, IEC 62471, IEC 60601-2-57	Compliant with IEC60601-1, IEC60601-1-11, IEC62471, IEC 60601-2-57	Compliant with IEC 60601- 1, IEC 62471, IEC 60601-2-57, IEC 60601-1-11	Compliant with IEC 60601- 1, IEC 60601-1-11, IEC60601-2-83	Compliant with IEC 60601- 1, IEC 60601-2-83, IEC 60601-1-11, IEC 62471	Compliant with IEC 60601- 1, IEC60601-2-57, IEC 60601-1-11	Compliant with IEC 60601- 1, IEC60601-2-57	Same

Note 1: Although the housing materials of the main unit of the subject device differ from those of the predicate devices, all materials comply with the requirements of ISO 10993-1, ISO 10993-5, ISO 10993-10, and ISO 10993-23. Therefore, this difference do not raise any safety or effectiveness concerns.

Note 2: Although the power source and treatment time of the subject device differ slightly from those of the predicate devices, all comply with the requirements of IEC 60601-1, IEC 60601-1-2, and IEC 62133-2. Therefore, these differences do not raise any safety or effectiveness concerns.

Note 3: Although the irradiance differs from the predicate devices, it remains within the acceptable deviation range; therefore, this difference will not raise any safety or effectiveness issues.

7. Test Summary

7.1 Non-Clinical Tests Performed

1) Electrical safety, and electromagnetic compatibility Test

Non-clinical tests were performed on the subject device for validate the design and to assure conformance with the following voluntary design standards in connection with medical device electrical safety, and electromagnetic compatibility:

- IEC 60601-1 2020-08 Edition 3.2 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- IEC 60601-1-11 Edition 2.1 2020-07 Medical Electrical Equipment --Part 1: 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.
- IEC 60601-2-57 Edition 2.0 2023-01 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.
- IEC 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems.
- IEC 62133-2 Edition 1.0 2017-02 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems.

2) Biocompatibility Test

- ISO 10993-1: 2018 Fifth Edition Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management.
- ISO 10993-5: 2009 Third Edition Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity.
- ISO 10993-10: 2021 Third Edition Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
- ISO 10993-23: 2021 First Edition Biological evaluation of medical devices- Part 23: Tests for irritation.

3) Software verification and validation

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions - Guidance for Industry and Food and Drug Administration Staff." The software for this device was considered as a Basic Documentation Level, since a malfunction of, or a latent design flaw in, the Software Device leads to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

4) Usability validation

- IEC 62366-1: 2015+AMD1:2020 Edition 1.1 Medical devices - Part 1: Application of usability engineering to medical devices.
- IEC 60601-1-6: 2010+AMD1:2013+AMD2:2020 CSV Edition 3.2 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.

7.2 Summary of Clinical Performance

Clinical testing was not needed for this 510(k). The non-clinical performance testing described above is sufficient to support that the device can be used safely and effectively.

8. Date of the summary prepared: December 14, 2024

9.Conclusion

The proposed device use technology that is similar to the predicate devices. The technology and design do not raise new types of questions regarding safety and effectiveness for the proposed indications for use and the performance testing supports that the device can be used safely and effectively for the proposed indications for use. The proposed device is considered to be substantially equivalent to the predicate device K230293, K240089, K241718, K241857, K203271 and K241293.