April 8, 2025

Shenzhen Nuon Medical Equipment Co., Ltd
Alain Dijkstra
CEO
1F-3F, No.27-2, Xintang Rd, Xintian Comm, Fuhai Str,
Baoan Dist
Shenzhen, GuangDong 518000
China

Re: K242151
Trade/Device Name: Radiant Renewal Skincare Wand (HD-44,HD-44A ,HD-44B,HD-44C, HD-69, HD-69A, HD-69B)
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: OLP, OHS
Dated: July 13, 2024
Received: July 23, 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: 2025.04.08 15:58:06 -04'00'

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K242151

Please provide the device trade name(s).

Radiant Renewal Skincare Wand (Models: HD-44,HD-44A,HD-44B,HD-44C,HD-69,HD-69A,HD-69B)

Please provide your Indications for Use below.

The Radiant Renewal Skincare Wand (Models: HD-44, HD-44A, HD-44B, HD-69, HD-69A) is an over-the-counter device intended for the treatment of full-face wrinkles.
The Radiant Renewal Skincare Wand (Models: HD-44C, HD-69B) is an over-the-counter device intended for the treatment of the mild to moderate inflammatory acne.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary
K242151

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 (K242151):

Trade Name:Radiant Renewal Skincare Wand (Models: HD-44, HD-44A, HD-44B, HD-44C, HD-69, HD-69A, HD-69B)
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 (K242700)
Sponsor: Shenzhen Nuon Medical Equipment Co., Ltd
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

Predicate Device 2 (K223893)
Sponsor: Light Tree Ventures Europe B.V.
Trade Name: Infrared Heat, model: E0221
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

4. Device Description

The Radiant Renewal Skincare Wand (Models: HD-44, HD-44A, HD-44B, HD-44C, HD-69, HD-69A, HD-69B) 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), yellow light (wavelength: 590nm±10nm), acne treatment through the emission of blue light (wavelength: 415nm±10nm).

Model HD-44 offers red and infrared light for wrinkle reduction. Models HD-44A and HD-69A only provide red light for wrinkle reduction. Models HD-44B and HD-69 use only yellow light for wrinkle reduction. And models HD-44C and HD-69B offers blue light for acne treatment. The ergonomic design of the device ensures ease of use, making them suitable for daily home skincare routines.

The package includes the main unit, a charging cable, a user manual, a tray. Each model is equipped with a single button to turn the device on or off. The device will automatically shut down after 5 minutes of operation.

5. Intended Use / Indications for Use

The Radiant Renewal Skincare Wand (Models: HD-44, HD-44A, HD-44B, HD-69, HD-69A) is an over-the-counter device intended for the treatment of full-face wrinkles.

The Radiant Renewal Skincare Wand (Models: HD-44C, HD-69B) is an over-the-counter device intended for the treatment of mild to moderate inflammatory acne.

6. Comparison to predicate devices

Compared 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 (K242151)**	**Predicate device 1 (K242700)**	**Predicate device 2 (K223893)**	**Remark**
Manufacturer	Shenzhen Nuon Medical Equipment Co., Ltd	Shenzhen Nuon Medical Equipment Co., Ltd	Light Tree Ventures Europe B.V.	--
510 (k) Number	K242151	K242700	K223893	--
Device Name	Radiant Renewal Skincare Wand	Radiant Renewal Skincare Lid	Infrared Heat	--
Regulation Class	Class II	Class II	Class II	Same
Product Code	OHS, OLP	OHS,OLP	OHS	Same
Intended Location Use	Face	Face	Face	Same
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Intended use	The Radiant Renewal Skincare Wand(Models:HD-44, HD-44A, HD-44B,HD-69, HD-69A) is an over-the- counter device	The Radiant Renewal Skincare Lid (Models: HD-59A, HD-59B, HD-72, HD-73A, HD-116, HD-	The Infrared Heat (Model: E0221) is intended to emit energy in the red and infrared spectrum for use	Same

	intended for the treatment of full-face wrinkles. The Radiant Renewal Skincare Wand (Models:HD-44C,HD-69B) is an over-the -counter device intended for the treatment of mild to moderate inflammatory acne.	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.	in the treatment of full face wrinkles.	
Housing Materials of Main Unit	PC & ABS & Silicon& Aluminum	PC & PP & Stainless Steel & ABS & Silicon& Aluminum&Silicone	Unknown	Similar, note1
Power Source	Lithium battery: For models HD-44,HD-44A, HD-44B,HD-44C: 3.7V, 30mAh; For models HD-69,HD-69A, HD-69B: 3.7V, 130mAh	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; For model HD-70: 3.7V, 95mAh	3.7V, 1800mAh lithium battery, 6.66Wh	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	Same
Type of Energy	LED	LED	LED	Same
LED wavelength	HD-44: Red+IR 630±10nm&830±10nm HD-44A/HD-69A: Red 630±10nm; HD-44B/HD-69: Yellow 590±10nm; HD-44C/HD-69B: Blue 415±10nm;	HD-59A: Red+IR 630±10nm&830±10nm HD-59B: Yellow 590±10nm HD-59D/HD-72A/HD-73B/HD-116A/HD-53B: 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/HD-73A/HD-116: Red light mode: 630±10nm; Yellow light mode: 590±10nm;	630nm±20nm/830 ± 20nm	Same

		HD-72/HD-73A/HD-116: Red light mode: 630±10nm; Yellow light mode: 590±10nm HD-53A: Red 630±10nm;		
Irradiance (mW/cm2)	HD-44: Red+IR 630±10nm: 20~50 830±10nm: 25~55 Total:45~105 HD-44A&HD-69A: Red 630±10nm: 30~50 HD-44B/HD-69: Yellow 590±10nm: 10~30 HD-44C/HD-69B: Blue 415±10nm: 35~50	HD-59A: Red+IR 630±10nm: 45~65 830±10nm: 30~50 Total:75~115 HD-59B:Yellow 590±10nm: 10~30 HD-59D/HD-72A/HD-73B/HD-116A/HD-53B: 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; HD-72/HD-73A/HD-116: Red light mode: 630±10nm: 15~40 Yellow light mode: 590±10nm: 8~30; HD-53A: Red 630±10nm: 20~40	630nm + 830nm: 30	Different, note 3
Treatment time	5 minutes per treatment	2 minutes per treatment	10 minutes per treatment per day	Different, note 2
Software/Firmware/Microprocessor Control?	Yes	Yes	Yes	Same
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	Same
Safety	Compliant with IEC 60601- 1, IEC 60601-1-11, IEC 62471, IEC 60601-2-57	Compliant with IEC 60601- 1, IEC 60601-1-11, IEC 62471, IEC 60601-2-57	Compliant with IEC 60601- 1, IEC 60601-1-11 IEC 62471, IEC 60601-2-57,	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 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.
- 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: April 7, 2025

9. Final Conclusion
The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated devices K242700 and K223893.