



September 24, 2026

Shenzhen Nuon Medical Equipment Co., Ltd.
Anna He
Regulatory Affairs Manager
1f-3f, #27-2, Xintang Rd., Xintian Comm, Fuhai St., Baoan Dist, Shenzhen, Guangdong
Shenzhen, Guangdong 518000
China

Re: K262183

Trade/Device Name: Hair Growth Helmet (TK-176, TK-600, TK-500, TK-282, TK-500A, TK-282A,
TK-126, TK-60)

Regulation Number: 21 CFR 890.5500

Regulation Name: Infrared Lamp

Regulatory Class: Class II

Product Code: OAP

Dated: June 29, 2026

Received: June 29, 2026

Dear Anna He:

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
L. HITHE -S

Digitally signed by
TANISHA L. HITHE -S
Date: 2026.09.24
15:45:47 -04'00'

Tanisha L. Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K262183

Device Name

Hair Growth Helmet

Models: TK-176, TK-600, TK-500, TK-282, TK-500A, TK-282A, TK-126, TK-60

Indications for Use (Describe)

Hair Growth Helmet (Models: TK-176, TK-282, TK-500A, TK- 282A, TK-126, TK-60),the red light and laser is indicated to promote hair growth in males with androgenetic alopecia who have Norwood- Hamilton Classifications of IIa - V patterns of hair loss and to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2 or frontal patterns of hair loss; both with Fitzpatrick Skin Types I - IV ;

Hair Growth Helmet (Models: TK-500, TK-600) is indicated to promote hair growth in males who have Norwood-Hamilton Classifications of IIa-V, and in females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II, and in both, Fitzpatrick Classification of Skin Phototypes I to IV

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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K262183
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: 3011644607

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

2. Subject Device Information:

Trade Name: Hair Growth

Helmet (Models: TK-60, TK-126, TK-282A, TK-500A, TK-282, TK-500, TK-600, TK-176)

Classification Name: Infrared Lamp

Review Panel: General & Plastic Surgery

Product Code: OAP、

Regulation Number: 21 CFR 890.5500,

Regulation Class: II

3. Predicate Device Information

Predicate Device 1 (K231321)

Sponsor: Shenzhen Kaiyan Medical Equipment Co.,Ltd

Trade Name: NOOANCE LED AND LASER HELMET (Model: M-120, M-282 PRO)

Classification Name: Infrared Lamp

Review Panel: General & Plastic Surgery

Product Code: OAP

Regulation Number: 21 CFR 890.5500

Regulation Class: II

Predicate Device 2 (K222081)

Sponsor: Freedom Laser Therapy, Inc.

Trade Name: ID-510 iRestore Elite

Classification Name: Infrared Lamp

Review Panel: General & Plastic Surgery

Product Code: OAP

Regulation Number: 21 CFR 890.5500

Regulation Class: II

Predicate Device 3 (K242363)

Sponsor: Shenzhen Kaiyan Medical Equipment Co.,Ltd Trade

Name: HIGHERDOSE RED LIGHT HAT (Model: HG-120K)

Classification Name: Infrared Lamp

Review Panel: General & Plastic Surgery
Product Code:OAP
Regulation Number: 21 CFR 890.5500
Regulation Class: II

Predicate Device 4 (K222477)

Sponsor: Dongguan Lescolton Medical Equipment Co.Ltd
Trade Name:Hair Growth Device
Classification Name: Infrared Lamp
Review Panel: General & Plastic Surgery
Product Code:OAP
Regulation Number: 21 CFR 890.5500
Regulation Class: II

4. Device Description

Hair Growth Helmet (Models: TK-176, TK-600, TK-500, TK-282, TK-500A, TK-282A, TK-126, TK-60) is a rechargeable, helmet-shaped device powered by a lithium-ion battery and intended for home use. It offers a non-invasive and convenient solution to support scalp health and promote hair growth in individuals with androgenetic alopecia in both women and men.

Models TK-176 and TK-282 deliver a combination of LED and laser energy to the scalp at a wavelength of 655nm (± 10 nm) to stimulate hair growth. Models TK-600 and TK-500 deliver a combination of LED energy at 625nm (± 10 nm) and 655nm (± 10 nm), and laser energy at 680nm (± 10 nm), to the scalp for hair growth stimulation. Models TK-500A, TK-282A, TK-126, and TK-60 deliver LED energy only at a wavelength of 655nm (± 10 nm) to the scalp for hair growth purposes.

The product package includes the main unit, a controller, a USB charging cable, a country-specific adapter, and a user manual.

5. Intended Use / Indications for Use

Hair Growth Helmet (Models: TK-176, TK-282, TK-500A, TK- 282A, TK-126, TK-60),the red light and laser is indicated to promote hair growth in males with androgenetic alopecia who have Norwood- Hamilton Classifications of IIa - V patterns of hair loss and to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2 or frontal patterns of hair loss; both with Fitzpatrick Skin Types I - IV ;

Hair Growth Helmet (Models: TK-500, TK-600) is indicated to promote hair growth in males who have Norwood-Hamilton Classifications of IIa-V, and in females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II, and in both, Fitzpatrick Classification of Skin Phototypes I to IV

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	Predicate Device 1	Predicate Device 2	Predicate Device 3	Predicate Device 4	Remark
Manufacturer	Shenzhen Nuon Medical Equipment Co.,Ltd.	Shenzhen Kaiyan Medical Equipment Co.,Ltd	Freedom Laser Therapy,Inc.	Shenzhen Kaiyan Medical Equipment Co.,Ltd	Dongguan Lescolton Medical Equipment Co., Ltd	--
Device Name	Hair Growth Helmet	NOOANCE LED AND LASER HELMET	ID-510 iRestore Elite	HIGHERD OSE RED LIGHT HAT	Hair Growth Device	--
510(k) Number	K262183	K231321	K222081	K242363	K222477	--
Regulation Number	890.5500	890.5500	890.5500	890.5500	890.5500	
Device Class	Class II	Class II	Class II	Class II	Class II	Same
Product Code	OAP,	OAP	OAP	OAP	OAP	Identical
Intended Use / Indications for Use	Hair Growth Helmet (Models: TK-176, TK-282, TK-500A, TK-282A, TK-126, TK-60),the red light and laser is indicated to promote hair growth in males with androgenetic alopecia who have Norwood- Hamilton Classifications of IIa - V patterns of hair loss and promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2 or frontal patterns of hair loss; both with Fitzpatrick Skin Types I - IV	The NOOANCE LED AND LASER HELMET is indicated to promote hair growth in males with androgenetic alopecia who have HamiltonNorwood Classifications of IIa-V and Fitzpatrick Classification of Skin Phototypes I to IV, and females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II and Fitzpatrick Classification	The ID-510 iRestore Elite is indicated to promote hair growth in males who have NorwoodHamilton Classifications of IIa-V, and in females with androgenetic alopecia who have LudwigSavin Classifications of I-II, and in both, Fitzpatrick Classification of Skin Phototypes I to IV.	The HIGHERD OSE Red Light Hat is a home wearable light-emitting diode phototherapy device with proven wavelengths of light 650nm±10nm Red light, which are used to treat Androgenetic Alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of IIa-V patterns of hair loss	The Hair Growth Device is indicated to promote hair growth in males with androgenetic alopecia who have Hamilton-Norwood Classifications of IIa-V and females with androgcnetic alopecia who have Ludwig-Savin Classifications of I-IIand Fitzpatrick Classification of Skin Phototypes I to IV. All users should also have Fitzpatrick Skin Types I	Identical

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Predicate Device 4	Remark
	Hair Growth Helmet (Models: TK-500A, TK-500, TK-600) is indicated to promote hair growth in males who have Norwood-Hamilton Classifications of IIa-V, and in females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II, and in both. Fitzpatrick classification of Skin phototypes I to IV	n of Skin Phototypes I to IV.		and to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2 or frontal patterns of hair loss; both with Fitzpatrick Skin Types I-IV.	to IV	
Intended location of use	scalp	scalp	scalp	scalp	scalp	Identical
Type of Device	Helmet	Helmet	Helmet	Hat	--	Identical
Energy Type	Low-level laser diodes and light emitting diodes	Low-level laser diodes and light emitting diodes	Light emitting diodes	Light emitting diodes	Light emitting diodes	Identical
Wavelength	TK-176: LDs and LEDs: 655±5nm; TK-600/ TK-500: LDs: 680±10nm; LEDs: 655±10nm, 625±10nm, TK-282: LDs: 655±10nm; LEDs: 655±10nm, TK-500A/TK-282A/TK-126/TK-60:	LDs: 650±5nm Red light LED: 650±5nm	LDs: 680±10nm LEDs: 625±10nm and 655±10nm	Red: 650±10nm	Laser: 650-660nm	Similar Note 1

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Predicate Device 4	Remark
	LEDs: 655±10nm,					
Laser Classification according to IEC 60825-1	Laser Class1 (TK-282, TK-176) Laser Class3R(TK-500,TK-600,)	Class 1C	Laser Class 3R	--	--	Similar Note 2
Irradiance	TK-60, TK-126, TK-176, TK-500A, TK-282, TK-282A: ≤ 5 mW/cm ² TK-500, TK-600: < 5 mW/light source	M-120: approximately 1.3mw/cm ² M-282PRO: approximately 2.8mw/cm ²	< 5 mW/light source	5mW/cm ²	LS-D620/LS-D630 : 40mW/cm ²	Similar Note 3
Treatment Time	TK-60/ TK-126: 10 minutes per treatment TK-176/ TK-600/ TK-500/ TK-500A: 12 minutes per treatment TK-282/TK-282A: 25 minutes per treatment	25 minutes every other day	12 minutes per treatment to be used daily	10 minutes every other day	LS-D620 : 20 minutes each time ,LS-D630 : 12 minutes	Similar Note 4
Treatment protocol	every other day for 16 weeks,	25 minutes every other day for 16 weeks	12 minutes per treatment to be used daily	10 minutes every other day for 16 weeks	LS-D620 : 20 minutes each time for 16 weeks LS-D630 : 12 minutes each time for 16 weeks	Similar Note 4
Power supply	Rechargeable Lithium-ion battery	Lithium-ion battery	Not available	Rechargeable Lithium-ion battery	Not available	Identical

Note1:

The subject device's wavelengths are as same as predicate device 2 (K222081),and within the bandwidth of predicate device 1 (K231321),predicate device 3 (K242363) ,predicate device 4 (K222477) . So, the difference between the subject device and the predicate devices will not raise any safety or effectiveness issues.

Note2:

Although the “Laser classification according to IEC 60825-1” of the subject device is different from the predicate device, the subject device conducted the safety test according to the IEC 60825-1 standards, and all the test results are in compliance with safety standards' requirements. So,the difference between the subject device and the predicate device will not raise any safety or effectiveness issues.

Note3

The Irradiance of Models TK-176,TK-600,TK-500,TK-282,TK-500A.TK-282,TK-126 and TK-60 are similar predicate device K231321,K222081,K242363,K211038,K222477. The Irradiance of subject product is in the range of predicate product .the difference will not raise any safety or effectiveness issues.

Note4:

The treatment protocol of models TK-282 and TK-282A are same as predicate device 1(K231321) ,The treatment protocol of models TK-176, TK-600,TK-500 and TK-500A is same as predicate device 2 (K222081). The treatment protocol of Models TK-60 and TK-176 are same as predicate device 3(K242363), and device 4(K222477).Although it has a slightly difference with predicate device, this 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 Edition 3.2 2020-08 CONSOLIDATED VERSION Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION 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 2023-07 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 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems.

IEC 61223-3-2 Second eidtion 2007-07 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.

IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance

IEC60601-2-22 Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

IEC 60825-1 Edition 2.0 2007-03 Safety of laser products - Part 1: Equipment classification and requirements

2) Biocompatibility Test

The subject device has been tested in compliance with the following standards and no additional risks concerning safety and effectiveness were noted;

ISO 10993-5:2009/(R)2014 Biological Evaluation of Medical Devices - Part 5: Tests Cytotoxicity

ISO 10993-10: 2010 (R2014), Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization

ISO 10993-23:2021+A1:2025 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

Usability testing was conducted on the The Hair Growth Helmet (Models:TK-60,TK-126,TK-282A,TK-500A,TK-282,TK-500,TK-600,TK-176), which complies with ANSI/AAMI/IEC 62366-1:2015 (R2021)+AMD1:2020 and IEC 60601-1-6 Edition 3.2 (2020-07) CONSOLIDATED VERSION

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: September 1, 2026

9. Final Conclusion

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated devices K231321,K222081,K242363,,K222477