July 31, 2023

Shenzhen Kaiyan Medical Equipment Co., Ltd
Alain Dijkstra
CEO
Building#3 and Building#5, 40th of Fuxin Street
Huaide Community, Fuyong Town, Baoan District
Shenzhen, Guangdong 518103
China

Re: K231321
Trade/Device Name: Nooance Led And Laser Helmet
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: May 6, 2023
Received: May 8, 2023

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Jianting Wang -S

Jianting Wang
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231321

Device Name
NOOĀNCE LED AND LASER HELMET (Model: M-120, M-282 PRO)

Indications for Use *(Describe)*
The NOOĀNCE LED AND LASER HELMET is indicated to promote hair growth in males with androgenetic alopecia who have HamiltonNorwood Classifications of Ila-V and Fitzpatrick Classification of Skin Phototypes I to IV, and females with androgenetic alopecia who have Ludwig-Savin Classifications of l-II and 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary of K231321

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

1. Submitter Information

Sponsor Name: Shenzhen Kaiyan Medical Equipment Co., Ltd
Address: Building#3 and Building#5, 40th of Fuxin Street, Huaide Community Fuyong Town, Baoan District, Shenzhen, Guangdong 518103, China
Contact name: Alain Dijkstra (CEO)
Tel: 0755-82129361
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Distributor

Company Name: NOOĀNCE INNOVATIONS

Address: 22 Rue Beaujon, 75008 Paris, France

Application Correspondent:

Contact Person: Mr. Alain Dijkstra
Shenzhen Kaiyan Medical Equipment Co., Ltd
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Tel: +86 755 82129361
Fax: +86 755 25024651
Email: regulation@kaiyanmedical.com

2. Summary Prepared Date

6 May, 2023

3. Subject Device Information

Trade Name: NOOĀNCE LED AND LASER HELMET
Model: M-120, M-282 PRO
Common Name: Laser, Comb, Hair
Classification Name: Infrared Lamp
Review Panel: General & Plastic Surgery
Product Code: OAP
Regulation Number: 21 CFR 890.5500
Regulation Class: II

4. Predicate Device Information

Predicate Device 1

Sponsor: Raymond R. Blanche
Common Name: Laser, Comb, Hair
Classification Name: Infrared Lamp
Trade Name: iRestore Professional 282

510(K) Number: K183417
Review Panel: General & Plastic Surgery
Product Code: OAP
Regulation Number: 21 CFR 890.5500
Regulation Class: II

Predicate Device 2
Sponsor: Chongqing Peninsula Medical Technology Co., Ltd.
Trade Name: Irradiation Cosmetic Device
Model: HairPro Plus
510(k) Number: K192552
Common Name: Laser, Comb, Hair
Classification Name: Infrared lamp
Review Panel: General & Plastic Surgery
Product Code: OAP
Regulation Number: 21 CFR 890.5500
Regulation Class: Class II

Predicate Device 3
Sponsor: Light Tree Ventures Europe B.V.
Trade Name: CurrentBody Skin™ LED Hair Regrowth
Model: MZ-07
510(k) Number: K230336
Common Name: Laser, Comb, Hair
Classification Name: Infrared lamp
Review Panel: General & Plastic Surgery
Product Code: OAP
Regulation Number: 21 CFR 890.5500
Regulation Class: Class II

5. Device Description
The NOOĀNCE LED AND LASER HELMET is an over-the-counter device designed to promote hair growth in person with androgenetic alopecia in women and men. The device is a combination of 650±5nm low-level laser diodes and 650±5nm light emitting diodes. Red light of specific spectrum combined with low-lever laser directly irradiated into hair follicles has been shown to help promote hair growth. It has two models, M-120 and M-282 PRO. The difference between them is the number of laser diodes (LDs) and light-emitting diodes (LEDs). The model M-120 is a combination of 51 class 1C low-level LDs and 69 LEDs. And the model M-282 PRO has 82 class 1C low-level LDs and 200 LEDs.

The device has two working modes. Mode 1 is continuous which has no frequency setting. Mode 2 is pulse with a frequency. User long presses the ON/OFF button to turn on the device and tap the ON/OFF button to select the preferred mode. Then press the start/pause button to start the treatment, treatment time is fixed for 25 minutes. The device is designed to automatically pause therapy if it is removed from the head and resume therapy when positioned on the head within 5 minutes and the start/pause button is pressed. Once the treatment complete, the device will turn off automatically with two “beep” sounds.

6. Indications for Use

The NOOĀNCE LED AND LASER HELMET is indicated to promote hair growth in males with androgenetic alopecia who have Hamilton-Norwood 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 of Skin Phototypes I to IV.

7. Comparison to Predicate Devices

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

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Verdict
Company	Shenzhen Kaiyan Medical Equipment Co., Ltd	Raymond R. Blanche	Chongqing Peninsula Medical Technology Co., Ltd.	Light Tree Ventures Europe B.V.	--
Trade Name	NOOĀNCE LED AND LASER HELMET	iRestore Professional 282	Irradiation Cosmetic Device	CurrentBody Skin™ LED Hair Regrowth	--
Model	M-120, M-282 PRO	/	HairPro Plus	MZ-07	--
510(k) Number	K231321	K183417	K192552	K230336	--
Common name	Laser, Comb, Hair	Laser, Comb, Hair	Laser, Comb, Hair	Laser, Comb, Hair	Same
Classification Name	Infrared Lamp	Infrared Lamp	Infrared lamp	Infrared lamp	Same
Review panel	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	Same
Product Code	OAP	OAP	OAP	OAP	Same
Regulation number	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500	Same
Regulation Class	Class II	Class II	Class II	Class II	Same
Intended Use / Indications for Use	The NOOĀNCE LED AND LASER HELMET is indicated to promote hair growth in males with androgenetic alopecia who have Hamilton-Norwood Classifications of IIa-V and Fitzpatrick Classification of Skin Phototypes I to IV,	The iRestore Professional 282 is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications	The Irradiation Cosmetic Device is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications	The CurrentBody Skin™ Led Hair Regrowth (MZ-07) is indicated to treat Androgenetic Alopecia and to Promote Hair Growth in	Same

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Verdict
	and females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II and Fitzpatrick Classification of Skin Phototypes I to IV.	of I-II, males who have Norwood-Hamilton Classifications of IIa-V and for both, Fitzpatrick Classification of Skin Phototypes I to IV.	of I - II and males with androgenetic alopecia who have Norwood-Hamilton Classifications of IIa – V and for both, Fitzpatrick Classification of Skin Phototypes I to IV	males who have Norwood-Hamilton Classifications of IIa - V patterns of hair loss 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.	
Type for use	OTC	OTC	OTC	OTC	Same
Intended User	Females & Males	Females & Males	Females & Males	Females & Males	Same
Type of light	Low-level laser diodes and light emitting diodes	Low-level laser diodes and light emitting diodes	Visible red laser	Visible red light-emitting diodes	Same as K183417
Wavelength	Laser: 650±5 nm Red light LED: 650±5 nm	650 ±10 nm	650±5 nm	660 nm	Same
Number of diodes	M-120: LDs: 51 LEDs: 69 M-282 PRO: LDs: 82 LEDs: 200	LDs: 82 LEDs: 200	272	120	Similar Note 1
Irradiance	M-120: approximately 1.3 mw/cm^2 M-282 PRO: approximately 2.8 mw/cm^2	Not available	2.7454 mw/cm2	1.67 mw/cm^2	Similar Note 2
Fluence	M-120: approximately	Not available	4.9417 J/cm2	1 J/cm^2	Similar

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Verdict
	1.9 J/cm^2 M-282 PRO: approximately 4.2 J/cm^2				Note 2
Distribution	Uniform distribution	Uniform distribution	Uniform distribution	Uniform distribution	Same
Laser classification according to IEC 60825-1	Class 1C	Class 3R	Class 3R	Not available	Different Note 3
Power output	< 5 mW from each laser or LED	Not available	5mW ±10%	Not available	Same
Treatment protocol	25 minutes every other day for 16 weeks	16 weeks, for 25 minutes treatment times, three times a week on alternate days	Each Treatment: 30 min Total Treatment: 3 times per week	Every day 10 mins	Same as K183417
Power Supply	Lithium-ion battery	Not available	Not available	lithium battery	Same as K230336

Comparison in Detail(s):

Note 1:

Although the “Number of diodes” of the subject device is different from the predicate device, since the specifications between them is different, but the energy is similar. So, the difference between the subject device and the predicate device will not raise any safety or effectiveness issues.

Note 2:

The “Irradiance” and the “Fluence” of Model M-282 PRO is similar predicate device K192552. The “Irradiance” and the “Fluence” of Model M-120 is similar predicate device K230336. Although not exactly the same, the parameters are very close. So, we think the little difference between the subject device and the predicate device will not raise any safety or effectiveness issues.

Note 3:

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.

8. Test Summary

8.1 Summary of Non-Clinical Performance Testing

1) Performance Testing Summary

The NOOĀNCE LED AND LASER HELMET (Model: M-120, M-282 PRO) has been evaluated the safety and performance by lab bench testing as following:

Title of the test	Device	Test	Acceptance	Unexpe	Test

	Description/Sample Size	Method/Applicable Standards	criteria	cted Results/ Significant Deviations	results
General requirements for basic safety and essential performance	The test sample is the final, finished product.	IEC 60601-1: Edition 3.2 2020-08	The test is carried out under the test method specified in the standard, and the test result is within the test acceptance range of the standard.	NA	Pass
Electromagnetic disturbances	The test sample is the final, finished product.	IEC 60601-1-2: Edition 4.1 2020-09	No degradation of performance was found during test or Lower than limits of measurement.	NA	Pass
Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	The test sample is the final, finished product.	IEC 60601-1-11: Edition 2.1 2020-07	The device operates normally, and can provide basic safety and essential performance.	NA	Pass
Particular Requirements for The Basic Safety And Essential Performance Of Non-Laser Light Source Equipment Intended For Therapeutic, Diagnostic, Monitoring And	The test sample is the final, finished product.	IEC 60601-2-57: Edition 1.0 2011-01	The test is carried out under the test method specified in the standard, and the test result is within the test acceptance range of the standard.	NA	Pass

Cosmetic/Aesthetic Use					
Photobiological safety of lamps and lamp systems.	The test sample is the final, finished product.	IEC 62471: First edition 2006-07	The test is carried out under the test method specified in the standard, and the test result is within the test acceptance range of the standard.	NA	Pass
Safety of laser products - Part 1: Equipment classification, and requirements	The test sample is the final, finished product.	IEC 60825-1: Edition 2.0 2007-03	The test is carried out under the test method specified in the standard, and the test result is within the test acceptance range of the standard.	NA	Pass

2) Biocompatibility

The component materials for Outer Shell of the helmet and the controller are identical to the corresponding component for Shell of the CurrentBody Skin™ Led Hair Regrowth (Model: MZ-07) in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents), that manufactured by Shenzhen Kaiyan Medical Equipment Co., Ltd and has been cleared in K230336 on April 05, 2023.

3) Usability Testing

Usability testing was conducted on the NOOĀNCE LED AND LASER HELMET (Model: M-120, M-282 PRO), the device complies with IEC 62366-1 and IEC 60601-1-6.

4) Software verification and validation testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA'S Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level concern, 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.

5) Cybersecurity

The subject device has no any external interfaces, according to FDA guidance “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices”.

7.2 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.

9. Conclusion

When compared to the predicate devices, the subject device does not raise new types of questions with regard to safety and effectiveness. After an analysis of intended use, performance, safety, and technological characteristics, the sponsor believes that it has demonstrated that the subject device can be operated safely and effectively for the proposed indications for use, and that it be considered as substantially equivalent to the legally marketed predicated devices K183417, K192552 and K230336.