January 23, 2026

Shenzhen Kaiyan Medical Equipment Co., Ltd.
Anna He
Official Correspondent
Bldg.#3 And Bldg.#5, 40th Of Fuxin St.,
Huaide Community, Fuyong Town, Baoan District
Shenzhen,
China

Re: K253669
Trade/Device Name: Trudermal Halo Hair Growth System (m-180a); Aduro Hair Growth (m-130,m-300)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: November 13, 2025
Received: November 21, 2025

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 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: 2026.01.23 14:28:19 -05'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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Office of Product Evaluation and Quality
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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)*
K253669

Device Name
Aduro Hair Growth; Trudermal Halo Hair growth system, Model Name: M-130,M-300;M-180A

Indications for Use *(Describe)*
The device are indicated to treat Androgenetic Alopecia and promote hair growth in 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 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.

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510(k) Summary - K253669

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

Sponsor Name: Shenzhen Kaiyan Medical Equipment Co., Ltd.

Establishment Registration Number: 3011644607

Address: Building #3, and Building#5, 40th of Fuxin Street, Huaide Community, Fuyong Town, Baoan District, Shenzhen, Guangdong, 518103, China

Contact Person (including title): Alain Dijkstra (CEO)

Tel: 0755-82129361

Fax: 0755-25024651

E-mail: alaindijkstra@kaiyanmedical.com

Manufacturer:

Manufacturer Name: Shenzhen Kaiyan Medical Equipment Co., Ltd.

Establishment Registration Number: 3011644607

Address: Building #3, and Building#5, 40th of Fuxin Street, Huaide Community, Fuyong Town, Baoan District, Shenzhen, Guangdong, 518103, China

Contact Person (including title): Alain Dijkstra (CEO)

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Application Correspondent:

Contact Person: Alain Dijkstra

Company: 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

Tel: +86 755 82129361

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Email: registrar@kaiyanmedical.com

2. Date of the summary prepared: January 21, 2026

3.Subject Device Information

Classification Name: Laser, Comb, Hair

Trade Name: Aduro Hari Growth; Trudermal Halo Hair growth system
Model Name: M-130,M-300;M-180A

Review Panel: General & Plastic Surgery

510(K) Number：K253669

Product Code: OAP

Regulation Number: 890.5500

Regulatory Class: II

4. Predicate Device Information

Predicate Device 1 Information

Sponsor: HIGHERDOSE LLC

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

Classification Name: Laser, Comb, Hair

510(K) Number: K242363

Review Panel: General & Plastic Surgery

Product Code: OAP

Regulation Number: 890.5500

Regulation Class: II

Predicate Device 2 Information

Sponsor: Kam Yuen Plastic Products Ltd.

Trade Name: Laser hair growth helmet (Model: A-800)

Classification Name: Laser, Comb, Hair

510(K) Number: K213025

Review Panel: General & Plastic Surgery

Product Code: OAP

Regulation Number: 890.5500

Regulation Class: II

5. Device Description

The Aduro Hair Growth (Model: M-130) is a device designed to be used with a baseball cap that emits led light with the intention to promote hair growth. The device provides distributed led to the scalp at 660nm±10nm. The device is designed as a head-mounted product, and it consists of the main unit, a controller and a power cable, as well as it is powered by the built-in rechargeable lithium battery. The device has only one key for switching on and off the device and it will automatically shut down after a 10-minute treatment is completed.

The Trudermal Halo Hair growth system (Model: M-180A) is a device designed to be used with a baseball cap that emits led light with the intention to promote hair growth. The device provides distributed led to the scalp at 660nm±10nm. The device is designed as a head-mounted product, and it consists of the main unit, a controller and a power cable, as well as it is powered by the built-in rechargeable lithium battery. The device has only one key for switching on and off the device and it will automatically shut down after a 10-minute treatment is completed.

The Aduro Hair Growth (Model: M-300) is a device designed to be used with a baseball cap that emits led light and Laser with the intention to promote hair growth. The device provides distributed led and laser to the scalp at 650nm (±10nm). The device is designed as a head-mounted product, and it consists of the main unit, a controller and a power cable, as well as it is powered by the built-in rechargeable lithium battery. The device has only one key for switching on and off the device and it will automatically shut down after a 25-minute treatment is completed.

6. Intended Use / Indications for Use

For M-130,M-300,M-180A

The device are indicated to treat Androgenetic Alopecia and promote hair growth in 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.

7. Comparison to predicate device and conclusion

Compare with predicate device, the subject device is very similar in design principle, intended use, indications for use, functions, material 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 Device1	Predicate Device 2	Remark
Company	ShenZhen Kaiyan Medical Equipment Co.,Ltd.	Shenzhen Kaiyan Medical Equipment Co., Ltd	Kam Yuen Plastic Products Ltd.	--
Trade Name	Aduro Hari Growth，Trudermal Halo Hair growth system	HIGHERDOSE Red Light Hat	Laser hair growth helmet	--
Classification Name	Laser, Comb, Hair	Laser, Comb, Hair	Laser, Comb, Hair	--
510(k) Number	K253669	K242363	K213025	--
Product Code	OAP	OAP	OAP	Same
FDA Device Classification	Class II	Class II	Class II	Same
Use	Over the Counter	Over the Counter	Over the counter	Same
Intended Use / Indications for Use	The deivce are indicated to treat Androgenetic Alopecia and promote hair growth in 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.	The HIGHERDOSE Red Light Hat is used to treat Androgenetic Alopecia and promote hair growth in 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.	The Laser hair growth helmet (Model: A-800) is intended for the promotion of hair growth in females with androgenic alopecia who have LudwigSavin Classifications I-II, and in males with androgenetic alopecia who have Norwood Hamilton Classifications IIa-V; and both genders having Fitzpatrick Classification of Skin Phototypes I-IV	Same

Intended location of use	scalp	scalp	scalp	Same
Energy Type	M-130,M-180A: Light emitting diodes M-300: Light emitting diodes+LLLT	Light emitting diodes	LLLT	Same
Wavelengths	M-130,M-180A:Red 660nm+/-10nm M-300: Red+laser 650 nm +/-5nm	Red: 650nm+/-10nm	650nm±10nm	Same
Total Intensity (mW/cm2)	<5 mW/cm^2	5 mW/cm^2	2.02 mW/cm^2	Similar Note1
Treatment Time	M-130,M-180A:10 minutes M-300: 25 minutes	10 minutes	Each Treatment: 25 min	Same
Dose	M-130,M-180A:3J/cm^2 M-300: 7.5J/cm^2	Red: 3J/cm^2	3.03J / cm^2	Similar Note2
Visible Light source	M-130: 130 Red LEDS M-180A: 180 Red LEDS M-300: 200 Red LEDS +100 Laser	120 Red LEDs	180 pcs	Similar Note3
Distribution	Uniform distribution	Uniform distribution	Not available	Same
Treatment protocol	every other day, for 16 weeks	every other day, for 16 weeks	Total Treatment: every two days	Same
Software controller	Device uses a timer and software to control treatment duration	Device uses a timer and software to control treatment duration	Not available	Same
Power supply	Rechargeable Lithium battery	Rechargeable Lithium battery	Not available	Same

Note1:
The total intensity of subject device is same as predicate device 1(K242363), and large than predicate device 2(K213025),it still falls within the range of the subject device, So, the difference between the subject device and the predicate devices will not raise any safety or effectiveness issues.

Note2:
The dose of subject device(M-130,M-180A)same as predicate device 1(K242363), similar to predicate device 2(K213025), the difference between the subject device and the predicate devices will not raise any safety or effectiveness issues.

Note3:
Although the amount of diodes of subject device is slightly different from the predicate devices, the amount is larger than predicate device 1(K242363), and similar to predicate device 2(K213025), it still falls within the range of the value for these 2 predicate devices (the number of diodes is not too high or too low compared to the predicate devices). So, the slightly difference between the subject device and the predicate devices will not raise any safety or effectiveness issues.

8. Test Summary

8.1 Summary of Non-Clinical Performance Testing

1) Performance Testing Summary

Aduro Hari Growth（Models:M-130,M-300) and Trudermal Halo Hair growth system(Model:M-180A) have been evaluated the safety and performance by lab bench testing as following:

Title of the test	Test Method/Applicable Standards	Acceptance criteria	Unexpected Results/Significant Deviations	Test results
General requirements for basic safety and essential performance	IEC 60601-1:2005/AMD1:2012/AMD2:2020	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	IEC 60601-1-2:2014+A1:2020	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.	IEC 60601-1-11:2015/AMD1:2020	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 Cosmetic/Aesthetic Use	IEC 60601- 2-57:2011	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
Photobiological safety of lamps and lamp systems.	IEC 62471:2006	The test is carried out under the test method specified in the standard, and	NA	Pass

		the test result is within the test acceptance range of the standard.		
Performance Test	The Performance Test Report performs the following tests on the finished product: Power Density Test; Leakage current test.	The device can meet the requirement of the performance test, Power Density test and Leakage current test.	NA	Pass

2) Biocompatibility testing

The component materials of the subject device are identical to the corresponding component materials of the e previously cleared devices (K223893, K202390) in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents). There is no change in biocompatibility since the previously cleared devices. Therefore, based on this information, the subject device can comply with the biocompatibility requirements of ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Sensitization), and ISO 10993-23 (Irritation).

3) Usability Testing

Usability testing was conducted on Aduro Hari Growth（Models：M-130,M-300）and Trudermal Halo Hair growth system(M-180A) 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, "Content of Premarket Submissions for Device Software Functions: Guidance for Industry and Food and Drug Administration Staff"

8.2 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. Final Conclusion：

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices K242363 and K213025.