November 20, 2024

Shenzhen Kaiyan Medical Equipment Co., Ltd
% Mary Kaps
Higherdose LLC
42 Broadway, 12th Floor, #212
New York, New York 10004

Re: K242363
Trade/Device Name: HIGHERDOSE Red Light Hat (HG-120K)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: July 17, 2024
Received: August 9, 2024

Dear Mary Kaps:

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: 2024.11.20 13:11:19 -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.

Submission Number *(if known)*

K242363

Device Name

HIGHERDOSE RED LIGHT HAT (HG-120K)

Indications for Use *(Describe)*

The HIGHERDOSE 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 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.

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510(k) Summary K242363

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 KAIYAN MEDICAL EQUIPMENT CO., LTD
Establishment Registration Number: 3011644607
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Contact Person (including title): Alain Dijkstra (CEO)
Tel: +86 755 82129361
Fax: +86 755 25024651
E-mail: **alaindijkstra@kaiyanmedical.com**

Distributor

Company Name: HIGHERDOSE LLC
Address: 42 Broadway, 12th Floor, #212, NewYork, NY 10004
Establishment Registration Number: 3019734322
Contact Person: Sumish Khadka
E-mail: **sumish@higherdose.com**

Manufacturer:

Manufacturer Name: SHENZHEN KAIYAN MEDICAL EQUIPMENT CO., LTD
Address: Building 3, No.40, Fuxin Street, Huaide Community, Fuyong Town, Baoan District, Shenzhen, Guangdong, 518103, China
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Application Correspondent:

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Tel: +86 755 82129361

Fax: +86 755 25024651
Email: registrar@kaiyanmedical.com

2. Date of the summary prepared: August 26, 2024

3.Subject Device Information

Classification Name: Infrared Lamp
Trade Name: HIGHERDOSE Red Light Hat
Model Name: HG-120K
Review Panel: General & Plastic Surgery
Product Code: OAP
Regulation Number: 890.5500
Regulatory Class: II

4. Predicate Device Information

Predicate Device 1 Information

Sponsor: Biophotas Inc
Trade Name: Biophotas Celluma
RESTORE
Classification Name: Infrared Lamp
510(K) Number: K211038
Review Panel: General & Plastic Surgery
Product Code: OAP
Regulation Number: 890.5500
Regulation Class: II

Predicate Device 2 Information

Sponsor: ADVIHAIR S.R.L.
Trade Name: Tricoglam Home Use
Classification Name: Infrared Lamp
510(K) Number: K193008
Review Panel: General & Plastic Surgery
Product Code: OAP
Regulation Number: 890.5500
Regulation Class: II

Predicate Device 3 Information

Sponsor: PhotonMD, Inc
Trade Name: Revian Red

Classification Name: Infrared Lamp
510(K) Number: K173729
Review Panel: General & Plastic Surgery
Product Code: OAP
Regulation Number: 890.5500
Regulation Class: II

Predicate Device 4 Information
Sponsor: Kam Yuen Plastic Products Ltd.
Trade Name: Laser hair growth helmet
Classification Name: Infrared Lamp
510(K) Number: K213025
Review Panel: General & Plastic Surgery
Product Code: OAP
Regulation Number: 890.5500
Regulation Class: II

5. Device Description
The HIGHERDOSE 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 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 device is designed as wearable product, and it consists of the main unit, the controller and a power cable, as well as it is powered by the built-in rechargeable lithium battery.

The hat compromises of 2 surfaces. An inner surface that contacts the skin and an outer surface. Both surfaces are constructed of cotton.

The controller contains a rechargeable Lithium battery, the power supply (adaptor) is used to charge the Lithium battery and is connected to a suitable mains outlet via a 2 or 3 pin input socket and wall plug. The HIGHERDOSE Red Light Hat cannot be operated while charging. The controller switches the LEDs ON/OFF. Switch the controller ON and allow the hat to run for 10 minutes treatment program. The cable for connecting with the controller is detachable.

The device is not used to make measurements of any sort, or to draw any conclusions regarding the indication to treat. The device does not require checks on the light output as the LEDs do not dim with age to any practical extent.

6. Intended Use / Indications for Use

The HIGHERDOSE 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 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	Predicate Device 3	Predicate Device 4	Remark
Company	Shenzhen Kaiyan Medical Equipment Co,. Ltd	Biophotas Inc	ADVIHAIR S.R.L.	PhotonMD, Inc	Kam Yuen Plastic Products Ltd.	--
Trade Name	HIGHERDOSE Red Light Hat	Biophotas Celluma RESTORE	Tricoglam Home Use	Revian Red	Laser hair growth helmet	--
Classification Name	Laser, Comb, Hair	Laser, Comb, Hair	Laser, Comb, Hair	Laser, Comb, Hair	Laser, Comb, Hair	--
510(k) Number	TBD	K211038	K193008	K173729	K213025	--
Product Code	OAP	OAP	OAP	OAP	OAP	Same
FDA Device Classification	Class II	Class II	Class II	Class II	Class II	Same
Use	Over the Counter	Over the Counter	Prescription, Rx	Over the counter	Over the counter	Same
Intended Use / Indications for Use	The HIGHERDOSE Red Light Hat is used to treat Androgenetic Alopecia and	The BioPhotas Celluma RESTORE is indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood-	Tricoglam Home Use is indicated to promote hair growth in females with and rogenetic alopecia who	The REVIAN RED device is indicated to treat Androgenetic Alopecia and to Promote Hair	The Laser hair growth helmet (Model: A-800) is intended for the promotion of hair growth in females	Same

	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.	Hamilton Classifications of IIa - V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in females who have LudwigSavin Scale I-1 to I-4, II-1, II-2 or frontal patterns of hair loss; both with Fitzpatrick SkinTypes I - IV.	have LudwigSavin Classification s I - II, in males with androgenetic alopecia who have Norwood Hamilton Classification s IIa - V and for both, Fitzpatrick Classification of Skin Phototypes of I - IV.	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 LudwigSavin Scale I-1 to I-4, II -1, II2 or frontal patterns of hair loss; both with Fitzpatrick Skin Types I - IV.	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	
Intended location of use	scalp	scalp	scalp	scalp	scalp	Same
Energy Type	Light emitting diodes	Light emitting diodes	Light emitting diodes	Light emitting diodes	LLLT	Same
Wavelengths	Red: 650nm+/-10nm	Red: 640nm+/-25nm (615-665nm)	650 nm +/-10nm	620-660 nm	650nm±10nm	Similar Note1

Total Intensity (mW/cm2)	5 mW/cm^2	2.77 mW/cm^2	525 mW	Not available	2.02 mW/cm^2	Similar Note2
Treatment Time	10 minutes	30 min	20 minutes in continuous every day	Every day 10 mins	Each Treatment: 25 min	Similar Note3
Dose	Red: 3J/cm^2	4.98 J/cm^2	1,2 J / cm^2	Not available	3.03J / cm^2	Similar Note4
Visible Light source	120 Red LEDs	Not available	105 Red LEDs	119 Red LEDs	180 pcs	Similar Note5
Distribution	Uniform distribution	Not available	Not available	Uniform distribution	Not available	Same
Treatment protocol	every other day, for 16 weeks	every other day, for 16 weeks	16 weeks	Not available	Total Treatment: every two days	Similar Note6
Software controller	Device uses a timer and software to control treatment duration	Device uses a timer and software to control treatment duration	Not available	Not available	Not available	Same
Power supply	Rechargeable Lithium battery	Not available	Rechargeable battery	Lithium Polymer	Not available	Same

Comparison in Details:
Note1:
The subject device's wavelengths are the same as predicate device 2(K193008) and predicate device 4(K213025), and within the bandwidth of predicate device 1 (K211038) and predicate device 3 (K173729). So, the difference between the subject device and the predicate devices will not raise any safety or effectiveness issues.

Note2:
The total intensity of subject device is larger than predicate device 1(K211038), predicate device 2(K193008) and predicate device 4(K213025). However, the subject device has the same / similar treatment parameters in “wavelength”, “amount of diodes”, “distribution” and

“treatment time” as the predicate device 3(K173729). So, the difference between the subject device and the predicate devices will not raise any safety or effectiveness issues.

Note3:
The treatment time of subject time is the same as predicate device 3(K173729) and slightly different from other predicate devices, however, this slight difference won't raise any safety or effectiveness issues.

Note4:
The dose of subject device is larger than predicate device 2(K193008), similar to predicate device 4(K213025), and smaller than predicate device 1(K211038). the dose of subject device is within the range of dose of the 4 predicate device. Therefore, the difference between the subject device and the predicate devices will not raise any safety or effectiveness issues.

Note5:
Although the amount of diodes of subject device is slightly different from the predicate devices, the amount is larger than predicate device 2(K193008), predicate device 3 (K173729) and smaller than predicate device 4(K213025), it still falls within the range of the value for these 4 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.

Note6:
The treatment protocol of subject device is same as predicate device 1(K211038) and predicate device 2(K193008). Although it has a slightly difference with predicate device 4(K213025), this will not raise any safety or effectiveness issues.

Final Conclusion:
The subject device is the same or similar to the legally marketed predicate device K211038, K193008, K173729 and K213025.

8. Test Summary

8.1 Summary of Non-Clinical Performance Testing

8.1.1Safety and Performance Test

The HIGHERDOSE Red Light Hat has been evaluated the safety and performance by lab bench testing as following:

1). IEC 60601-1:2005+AMD1:2012+AMD2:2020 CSV（include IEC 60601-1-6:2010+A1:2013+A2:2020）Medical electrical equipment - Part 1). General requirements for basic safety and essential performance

2). IEC 60601-1-2:2014/AMD1:2020 Amendment 1 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

3). IEC 60601-1-11:2015/AMD1:2020 Medical electrical equipment - Part 1-11: 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

4). IEC 60601-2-57:2023 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, cosmetic and aesthetic use

5). IEC 62471:2006 Photobiological safety of lamps and lamp systems.

All the test has been passed.

8.1.2Usability Test

Usability testing was conducted on the HIGHERDOSE Red Light Hat (Model: HG-120K), the device complies with IEC 62366-1 and IEC 60601-1-6.

8.1.3Software verification and validation testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance "Content of Premarket Submissions for Device Software Functions - Guidance for Industry and Food and Drug Administration Staff."

8.1.4Cybersecurity

The subject device no any external interfaces, no need cybersecurity evaluation.

8.2Biocompatibility testing

The component materials of the subject device are identical to the corresponding component materials of the previously cleared devices (K223893) in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents). here 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).

8.3 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 K211038, K193008, K173729 and K213025.