October 11, 2024

Dongguan Tutamen Metalwork Co., Ltd
Caitlyn Dzhafarov
Sr. Regulatory Consultant
No.3, Huangguotang Road
Tangxia Town
DongGuan, 523000
China

Re: K240472
Trade/Device Name: PBM Hair Therapy Cap
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: October 10, 2024
Received: February 20, 2024

Dear Caitlyn Dzhafarov:

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: 2024.10.11 00:02:43 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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Infection Control Devices
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.

Submission Number *(if known)*

K240472

Device Name

PBM Hair Therapy Cap

Indications for Use *(Describe)*

The PBM Hair Therapy Cap is indicated to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig-Savin Scale I to II, males who have Norwood Hamilton Classifications of IIa to V patterns of hair loss, females and males with frontal patterns of hair-loss both with Fitzpatrick Skin Types 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.

510(k) #: K240472

510(k) Summary

Prepared on: 2024-10-10

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Dongguan Tutamen Metalwork Co., LTD.
Applicant Address	No.3, Huangguotang Road Tangxia Town DongGuan 523000 China
Applicant Contact Telephone	760-402-7859
Applicant Contact	Mr. Stephen Prior
Applicant Contact Email	stephenprior@tutamen.net
Correspondent Name	Medical Devices Pathway, LLC.
Correspondent Address	14330 178th Ln NE Woodinville WA 98072 United States
Correspondent Contact Telephone	3602243622
Correspondent Contact	Ms. Caitlyn Dzhafarov
Correspondent Contact Email	cdzhafarov@meddevpath.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	PBM Hair Therapy Cap
Common Name	Infrared lamp
Classification Name	Laser, Comb, Hair
Regulation Number	890.5500
Product Code	OAP

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K173729	Revian Red	OAP

Device Description Summary

21 CFR 807.92(a)(4)

The PBM Hair Therapy Cap is a hair therapy device that uses red light to help stimulate hair growth in both male and females. The device comes with a Cap that has LED diodes inbuilt and an attachable controller battery pack that comes with an automatic timer that limits the user to 15-minute sessions.

The device uses only 660nm LED wavelength diodes on 7 strips, each strip has 12 diodes, with a total of 84 diodes. These diodes strips are sewn into a cap and has a Type C USB connector that the controller battery pack can connect to.

The PBM Hair Therapy Cap is comprised of a fabric cap with inbuilt LED diodes that emit red light on the wavelength of 660nm. The diodes are on strips and the cap style hat has 7 strips with 12 diodes on each strip with a total of 84 LED diodes.

A battery powered controller that attaches via a C-type USB connector to the fabric hat is also provided. The controller has a built in 3.7V

lithium-ion battery, has an on/off button and in programmed to automatically turn of after 15min of use. The controller also has a 2 small indicator LED's for indicating, power on/in use, needs charging, and also blinks while in charging mode. The controller charges via inbuilt C-Type USB port and charges at 500 mA.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The PBM Hair Therapy Cap is indicated to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig-Savin Scale I to II, males who have Norwood Hamilton Classifications of IIa to V patterns of hair loss, females and males with frontal patterns of hair-loss both with Fitzpatrick Skin Types I to IV.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use statements are substantially equivalent, just worded slightly differently. Both are indicated for the same patient populations and have the same intended use.

Technological Comparison 21 CFR 807.92(a)(6)

Both the PBM Hair Therapy Cap Device and Revian Red utilize LLLT mechanism of action with textile hair caps to target hair growth on the scalp in the same indicated patient population. The technical specifications of the PBM Hair Therapy Cap and the predicate Revian Red are comparable. The noted minor differences in technological characteristics, such as battery types (lithium-ion versus lithium polymer), wave-lengths (660 nm versus 620-660 nm), and number of red LEDs (84 versus 119 Red LEDs) and treatment durations (15 minutes versus 10 minutes), are considered negligible and do not affect the therapeutic value or safety profile. Both devices are classified as class 3R laser systems in accordance with IEC standards and share a substantially equivalent adverse event profile. Many of the characteristics which differ between the PBM Hair Therapy Cap and the predicate, The Time Machine Series Lasers device, are due to the PBM Hair Therapy Cap being a subset of the intended use and indications for use of the predicate device and fall within the cleared spectrum of technical characteristics of the predicate device (e.g. fall within the cleared wavelength, etc.). None of these differences raises new or different questions of safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Verification of requirements (VR0001) and usability testing (US001, in accordance with IEC 62366-1:2015 and Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff)

Not Applicable

With respect to the PBM Hair Therapy Cap comparison to a predicate device, Revian Red, the PBM Hair Therapy Cap has the same intended use, similar technological characteristics, and for minor differences in technological characteristics, these have been determined to not raise and different questions of safety or effectiveness. Scientific data supporting safety and effectiveness have been provided and are similar to the data required for the legally marketed predicate device. The totality of non-clinical data provides valid scientific evidence to support the conclusion that there are no different questions of safety and effectiveness raised when compared to the predicate device. This data demonstrates the PBM Hair Therapy Cap is substantially equivalent to the predicate Revian Red based upon the totality of the evidence.