December 2, 2024

Apira Science Inc
% Tracy Che
Registration Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center,
No. 3101-90, Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K242619
Trade/Device Name: GroWell BT Hair Growth System (GW10042)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP
Dated: August 30, 2024
Received: September 3, 2024

Dear Tracy Che:

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: 2024.12.02 15:18:45 -05'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*

K242619

Device Name

GroWell BT Hair Growth System (GW10042)

Indications for Use *(Describe)*

MEN - The GroWell BT Hair Growth System ("GroWell") is designed to promote hair growth in males with androgenetic alopecia who have Norwood Hamilton Classifications of IIa to V.
WOMEN - The GroWell is designed to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin classifications of I-II.
The GroWell is approved for 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) #:	510(k) Summary	Prepared on: 2024-12-02

Contact Details

21 CFR 807.92(a)(1)

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Correspondent Contact	Ms. Tracy Che
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	GroWell BT Hair Growth System (GW10042)
Common Name	Laser, Comb, Hair
Classification Name	Infrared lamp
Regulation Number	890.5500
Product Code(s)	OAP

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K140931	iGrow-II Hair Growth System	OAP
K141567	iGrow-II Hair Growth System	OAP
K173729	Revian Red	OAP

Device Description Summary

21 CFR 807.92(a)(4)

The GroWell BT Hair Growth System consists of 24 proprietary red light diode lasers and 39 proprietary red light super-luminescent diodes configured in a flexible panel which is inserted in an adult, baseball-style cap. The GroWell contains 655nm laser and LED diodes, which generates light after being excited by the internal power supply, the light is controlled and output by the control device, and directly and effectively irradiated to the treatment site, so as to achieve therapeutic effect. The GroWell's combination and configuration

of diode lasers and non-laser LED's provides for a full coverage of the upper 1/3 of the head; i.e, the scalp area roughly from the top of the head to the top of the ears. The GroWell session will be "paused" and the light array will automatically turn off if the user removes the GroWell during use, and will resume when it is replaced on the head. At the end of the 25 minute session, the lights will turn off and the GroWell will emit two audible beeps to signal that the therapy is complete.

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

MEN - The GroWell BT Hair Growth System ("GroWell") is designed to promote hair growth in males with androgenetic alopecia who have Norwood Hamilton Classifications of IIa to V.
WOMEN - The GroWell is designed to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin classifications of I-II.
The GroWell is approved for Fitzpatrick skin types I-IV.

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

The subject device and predicate devices have the same indications for use, both are mainly used to promote hair growth.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device and predicate devices have similar technological characteristics:
1) They use the same laser diodes and LEDs as the light source;
2) They all adopt the design of a cap/helmet which provides for a full coverage of the upper 1/3 of the head;
3) They have the same key performance parameters such as the wavelength and energy per diode.
The main differences between the subject device and predicate devices are power supply, dimensions and weight, and number of diodes.
1) Power supply: The power supply of the subject device is lithium battery, while the power supply of the predicate devices (K140931 and K141567) are main power. However the lithium battery of the subject device has passed IEC62133 test and the power adapter has been assessed for electrical safety test along with the main unit, so this difference does not raise any safety/effectiveness questions.
2) Number of diodes: The subject device has 24 lasers and 39 LEDs while the predicate devices (K140931 and K141567) has 21 lasers and 30 LEDs. It basically means the subject device can cover more area than the predicate devices.
3) Dimensions and weight: The dimensions of the subject device are similar to the predicate devices. The weight is lower than the weight of K140931 and K141567, both of which use a helmet, and higher than K173729, which uses a textile cap to mount the light panel. The weight is in between the weights of predicate devices. The difference in weight does not raise safety or effectiveness issues, because the core function, light output, is not affected by device dimension or weight.
Based on the above discussion, these differences do not raise safety and effectiveness issues and the subject device has passed corresponding international standards tests.

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

Non-clinical testing have been conducted to verify that the GroWell meets all design specifications which supports the conclusion that it's substantially equivalent to the predicate devices. The testing results demonstrate that the subject device complies with the following standards:
IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION Medical electrical equipment - Part 1: General requirements for basic safety and essential performance;
IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests;
IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION 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;
IEC 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems;
IEC 60825-1: 2014 Safety of laser products - Part 1: Equipment classification, and requirements

The device has been evaluated for biocompatibility as per ISO 10993-1 Fifth edition 2018-08 and tested as per ISO 10993-5 Third edition 2009-06-01, ISO 10993-10 Fourth edition 2021-11 and ISO 10993-23 First edition 2021-01.
The device software has been evaluated as per FDA guidance " Content of Premarket Submissions for Device Software Functions" .
In order to verify and assure the performance, function and quality of the product, we have conducted performance verification.
The clinical test is not applicable, there's no clinical data.

Based on the above analysis and tests, the subject device is substantially equivalent to the predicate devices.