April 28, 2023

Won Tech Co., Ltd.
Hyun Yoon
General Manager
64 Techno 8-Ro, Yuseong-gu
Daejeon, 34028
Korea, South

Re: K223862
Trade/Device Name: Hair Boom 69, Hair BoomAir, Hair Boom, Ulike Hair UpUp
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: March 29, 2023
Received: March 29, 2023

Dear Hyun Yoon:

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)*
K223862

Device Name
Hair Boom 69, Hair Boom Air, Ulike Hair UpUp

Indications for Use *(Describe)*
The Hair Boom 69 is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications I - II, in males with androgenetic alopecia who have Norwood-Hamilton Classifications of IIa - V and for both, 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

[As required by 21 CFR 807.92]

K223862

1. Date Prepared [21 CFR 807.92(a)(a)]

April 25th, 2023

2. Submitter's Information & Contact Person [21 CFR 807.92(a)(1)]

- Name of Manufacturer: WON TECH Co., Ltd.
- Address: 64 Techno 8-ro, Yuseong-gu, Daejeon, 34028, Republic of Korea
- Contact Name: Hyun Sik Yoon
- Telephone No.: +82-10-6750-5346
- Fax No.: +82-70-7836-0110
- Email Address: yoonhs21@wtlaser.com

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Common name: Lamp, non-heating, for promotion of hair growth
Trade name: Hair Boom 69, Hair Boom Air, Hair Boom, Ulike Hair UpUp

Classification Description	21 CFR Section	Product Code
Infrared lamp	890.5500	OAP

As stated in 21 CFR, parts 890.5500, this generic type of the device has been classified as Class II.

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4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follow:

Predicate device

- 510(k) Number: K192425
- Applicant: Hair Boom 69
- Classification Name: Infrared lamp per 21 CFR 890.5500
- Trade Name: Hair Boom 69, Hair Boom Air, Hair Boom, Ulike Hair UpUp

5. Description of the Device [21 CFR 807.92(a)(4)]

The Hair Boom 69 diode laser is configured within an outer helmet and protective inner liner. The use of diode lasers provides for a full coverage of the upper 1/3 of the head; i.e., the area commonly covered with stylized hair. At the end of the therapy cycle, the system signals that therapy is complete and ready to be powered down, by emitting an audible beep pattern.

6. Indications for Use [21 CFR 807.92(a)(5)]

The Hair Boom 69 is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications I - II, in males with androgenetic alopecia who have Norwood-Hamilton Classifications of IIa - V and for both, Fitzpatrick Classification of Skin Phototypes I to IV.

7. Determination of Substantial Equivalence [21 CFR 807.92(a)(6) and 21 CFR 807.92(b)]

There are no significant differences between the previous and renewed Hair Boom 69 that would adversely affect the use of the product. It is substantially equivalent to this device in design, function, and technical characteristics.

	Proposed Device	Predicate Device #1	SE Decision
K Number	K223682	K192425	N/A
Manufacturer	WON TECH Co., Ltd.	WON TECH Co., Ltd.	Same
Model Name	Hair Boom 69, Hair Boom Air, Ulike Hair Up Up	Hair Boom 69, Hair Boom Air, Ulike Hair Up Up	Same
Indications for Use	The Hair Boom 69 is indicated to promote hair growth in females with androgenetic alopecia	The Hair Boom 69 is indicated to promote hair growth in females with androgenetic alopecia	Same

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	Proposed Device	Predicate Device #1	SE Decision
	who have Ludwig-Savin Classifications ofl - II, males who have Norwood-Hamilton Classifications of Ila - V and for both, Fitzpatrick Classification of Skin Phototypes I to IV.	who have Ludwig-Savin Classifications ofl - II, males who have Norwood-Hamilton Classifications of Ila - V and for both, Fitzpatrick Classification of Skin Phototypes I to IV.	
Anatomical site	Head Skin	Head Skin	Same
Design	Helmet Design	Helmet Design	Same
Clearance	Females & Males OTC	Females & Males OTC	Same
Technical characteristics	The Hair Boom 69 diode laser is configured within an outer helmet and protective inner liner. The use of diode lasers provides for a full coverage of the upper 1/3 of the head; i.e., the area commonly covered with stylized hair. At the end of the therapy cycle, the system signals that therapy is complete and ready to be powered down, by emitting an audible beep pattern.	The Hair Boom 69 diode laser is configured within an outer helmet and protective inner liner. The use of diode lasers provides for a full coverage of the upper 1/3 of the head; i.e., the area commonly covered with stylized hair. At the end of the therapy cycle, the system signals that therapy is complete and ready to be powered down, by emitting an audible beep pattern.	Same
Wavelength	650 +/- 5nms	650 +/- 5nms	Same
Laser Mode	30 minutes only	30 minutes only	Same
Helmet Design			Same
Controller Design			Different Design Change. The controller of the predicate divice

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	Proposed Device	Predicate Device #1	SE Decision
			(K192425)is octagon shaped and the start / stop button, power button, and hold button were placed on the front panel of the controller. However, the renewed device, its shape has been changed from octagon to circle. As the design changes to a circled shape, the existing start / stop button and power button are located on the front side together as same as before, but the hold button is arranged on the side panel.
Classification	OAP, Infrared Lamp	OAP, Infrared Lamp	Same

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Non-Clinical Test Summary [21 CFR 807.92(b)(1)]

The WON TECH Co., Ltd. claims conformity with the following Electrical & Mechanical Safety, and Electromagnetic Compatibility standards:

1) Electrical Safety, Electromagnetic Compatibility Testing

As aim of this submission is limited to the controller design change, the result of electrical safety test reports and standards were demonstrated in the previous cleared submission under K192425

Standard (Edition)	Description
IEC 60601-1:2005/AMD2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
IEC 60825-1 Edition 2.0 2007	Safety of laser products - Part 1: Equipment classification and requirements

2) Software Validation

The Hair Boom 69 contains MINOR level of concern software. Software was designed and developed according to a software development process and was verified and validated.

The software information is provided in accordance with FDA guidance: The content of premarket submissions for software contained in medical devices, on May 11, 2005.

3) Biocompatibility

As aim of this submission is limited to the controller design change, the part that contacts the user is same as the previous cleared submission under K192425

Part	**Material**	**Patient Contact**	**Duration of Contact by ISO 10993-1**	**Bio-compatibility**
Foam lined spacers inside the helmet	Polyester / Spandex	Intact Skin	Limited (< 24 hours)	Yes

- The material is same as the predicate device (K192425) as they use same helmet design

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Clinical Test Summary [21 CFR 807.92(b)(2)]

No clinical studies were considered necessary and performed.

Conclusion [21 CFR 807.92(b)(3)]

In according with the Federal Food & drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification WON TECH Co., Ltd. concludes that the Hair Boom 69 is substantially equivalent to previous device (Hair Boom 69, K192425) as described herein.