September 30, 2019

Won Tech Co., Ltd.
Jake Yu
Staff of Regulatory Affairs
64 Techno 8-Ro, Yuseong-gu
Daejeon, 34028 KR

Re: K192425
Trade/Device Name: Hair Boom 69, Hair Boom Air, Ulike Hair UpUp
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: August 20, 2019
Received: September 5, 2019

Dear Jake Yu:

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,

Purva Pandya, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192425

Device Name

Hair Boom 69

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 Classifications of Skin Phototypes 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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K192425

510(k) Summary
WON TECH

Date Prepared: August 20, 2019

Submitter's Contact Information

Name: Jake Yu

Address: WON TECH Co., Ltd.
64 Techno 8-Ro, Yuseong-gu,
Daejeon, Republic of Korea

Telephone: 82-70-7836-6921

Facsimile: 82-70-934-9491

Trade Name: Hair Boom 69, Hair Boom, Hair Boom Air, Ulike Hair UpUp

Common or Usual Name: Lamp, non-heating, for promotion of hair growth

Classification Name: Infrared lamp per 21 CFR 890.5500

Classification Code: OAP (Laser, comb, hair)

Predicate Device:

Device Trade Name	Manufacturer
Hair Boom 69 (K191154)	WON TECH Co., Ltd.

Intended Use/ Indications for Use

The Hair Boom 69 is indicated to promote hair growth in females with androgenetic alopecia 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.

Technological 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.

Modification

The Hair Boom 69 had minor modifications in additional model names(Hair Boom Air/Ulike Hair UpUp) and helmet and storage base enclosure change. Ear pads and plastic enclosure of the pads were removed for more convenience. The external color of helmet was changed. And the storage base design was changed to match the shape of helmet. The removed parts of helmet did not contain any electrical components. Therefore the change of helmet and storage base enclosure does not affect to the electrical safety and performance.

Performance Data:

No clinical performance data was produced for this submission because the Hair Boom 69 is an identical device in optical, electronic and mechanical function as well as recommended clinical treatment regime, to the predicate device, the Hair Boom 69.

The Hair Boom 69 was tested to internationally recognized standards, consistent with the current recommendations adopted by the FDA.
IEC 60825-1 Edition 2.0 2007 - 03 Laser Safety & Classification
IEC 60601-1:2005 (currently called AAMI/ANSI standard) Basic Safety and Essential Performance
IEC 60601-1-2 Edition 1.0. 2010 -04 EMC. This replaces Edition 3.0 2007 - 03
IEC 60601-1-11 Edition 1.0 2014 - 06 Home Use. This replaces Edition 2010 - 04
IEC 62304 Edition 1.1 2015 -06 Software and Life Cycle Processes
ISO 14971 Second edition 2007 - 03 - 01 Application of Risk Management to Medical Devices
ISO 10993-5 2009 -Biological Evaluation of Medical Devices Part 5: Test For In Vitro Cytotoxicity
ISO 10993-10:2010/(R) 2014 -Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.

Substantial Equivalence

The Hair Boom 69 is equivalent to the device known as the Hair Boom 69 cleared under 510(k) number, K191154. It is as safe and effective as the predicate device.
Both systems, which use red light diode lasers which are classified as class IIIa/3R laser systems by the IEC standard for allowable emission levels, which is a recognized standard by the FDA as well, and the adverse event profile is the same.

Finally, data summarized in the 510(k) notice confirms the safety and efficacy of the Hair Boom 69 for minor modifications, according to special 510(k) process. For these reasons, the Hair Boom 69 satisfies the FDA's standard for substantial equivalence with respect to intended use, technological and design characteristics.

Treatment Protocol

The Hair Boom 69 with an intended for OTC use is the same device as the Hair Boom 69 proposed for OTC use. These devices are one and the same.

The following Comparison Chart in support of substantial equivalence is provided:

Hair Boom 69 (K191154)	**Hair Boom 69 (Proposed)**
LLLT Device Type	LLLT Device Type
OTC	OTC
Intended Use - Androgenetic Alopecia	Intended Use - Androgenetic Alopecia
Contain Laser Diodes- 69 Class 3R	Contain Laser Diodes- 69 Class 3R
Helmet Design	Helmet Design(removed ear pads and enclosures/Color of helmet enclosure)
Wavelength 650 +/- 5 nms.	Wavelength 650 +/- 5 nms.
Marketing Clearance -Females & Males OTC	Marketing Clearance -Females & Males OTC
Passive Use-Hands Free	Passive Use-Hands Free
OAP Classification	OAP Classification
Classification Name -Infrared Lamp	Classification Name -Infrared Lamp
Common Usage Name - Lamp, Non-Heating	Common Usage Name - Lamp, Non-Heating
General & Plastic Surgery Committee	General & Plastic Surgery Committee
Skin Phototypes - I- IV	Skin Phototypes - I- IV
Hamilton-Norwood Ila-V Hair Loss Classification Ludwig-Savin I - II Hair Loss Classification	Hamilton-Norwood Ila-V Hair Loss Classification Ludwig-Savin I - II Hair Loss Classification
Device Class II	Device Class II

Conclusion

With the data presented in the Comparison Chart, we believe that this demonstrates the Hair Boom 69, is substantially equivalent to the Hair Boom 69 and based upon the equivalent technological designs of the compared devices, the mild modifications applied and submitted in this application, we request the FDA to clear the device via the 510(k) notice.