December 8, 2020

Y&J BIO Co., Ltd.
℅ Paweena U-Thainual
CEO
MDR Solutions Co., Ltd
1435 Kanjanapisek Road, Bang Khae Nuea
Bangkok, Bang Khae 10160
Thailand

Re: K202983
Trade/Device Name: easy Hairfull
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: September 28, 2020
Received: September 30, 2020

Dear Paweena U-Thainual:

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)*
K202983

Device Name
easy Hairfull

Indications for Use *(Describe)*
The easy Hairfull is intended to promote hair growth in males with androgenetic alopecia who have Norwood Hamilton Classifications of IIa to V and Fitzpatrick Classification of Skin Phototypes I to IV, and in females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II and 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.

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5. 510(k) Summary

1. General Information

Applicant/Submitter:	Y&J BIO Co., Ltd.
Address:	B-916 ,947, Hanam-daero, Hanam-si, Gyeonggi-do, Republic of Korea Tel) +82-31-5180-3491
Contact Person:	Paweena U-Thainual, MDR Solutions Co., Ltd.
Address:	1435 Kanjanapisek Road, Bang Khae Nuea, Bang Khae, Bangkok, THAILAND 10160 Tel: +66-2-804-2101 Email: paweena@mdrsolutions.co.th
Preparation Date:	September 18, 2020

2. Device Name and Code

Device Trade Name:	easy Hairfull
Common Name:	Lamp, non-heating, for promotion of hair growth
Classification Name:	Infared lamp
Product Code:	OAP
Regulation Number:	890.5500
Classification:	Class II
Review Panel:	General & Plastic Surgery

3. Predicate Devices

Easy Hairfull is substantially equivalent to the following device

Table 5.1 Predicate devices

Applicant	Device Name	510(k) Number
Y&J BIO Co., Ltd.	Hair Up	K180617

4. Device Description

The easy Hairfull is basically an identical device with the 510(k)-cleared device Hair up (K180617). A new 510(k) clearance is applied this time with the difference in the location of the

controller and battery. The controller where the battery embedded is located on the headset at this time.

The easy Hairfull consists of 21 red visible laser diodes (LDs) and 30 red light emitting diodes (LEDs) configured within an outer helmet and protective inner liner. The use of LDs and LEDs provides for a full coverage of the upper 1/3 of the head where commonly covered with stylized hair. The system automatically pauses therapy when the device is not in the correct head position and resumes treatment when the correct head position is re-established. At the end of the therapy cycle, the system signals that therapy is complete and the device will automatically turn off.

The device could be powered by internal rechargeable li-on battery, and it can also be supplied by specified external adapter with Input AC 100-240V, 50/60Hz and Output DC 5V, 2A.

5. Indications / Intended Use

The easy Hairfull is intended to promote hair growth in males with androgenetic alopecia who have Norwood Hamilton Classifications of IIa to V and Fitzpatrick Classification of Skin Phototypes I to IV, and in females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II and Fitzpatrick Classification of Skin Phototypes I to IV.

6. Technical Characteristics in Comparison to Predicate Devices

Easy Hairfull is substantially equivalent to the following legally marketed predicate devices.

	Predicate Device	**Proposed Device**	**SE**
510(K) Number	K180617	K202983	
Manufacturer	Y&J BIO Co., Ltd.	Y&J BIO Co., Ltd.	YES
Device Name	Hair Up	easy Hairfull	
Clearance Date:	June 1, 2018	N/A	
Classification / Regulation	Class 2 / 890.5500	Class 2 / 890.5500	YES
Product Code	OAP	OAP	YES
Intended Use	The Hair Up is intended to promote hair growth in males with androgenetic alopecia who have Norwood Hamilton Classifications of IIa to V and Fitzpatrick Classification of Skin Phototypes I to IV, and in females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II and Fitzpatrick Classification of Skin Phototypes I to IV.	The easy Hairfull is intended to promote hair growth in males with androgenetic alopecia who have Norwood Hamilton Classifications of IIa to V and Fitzpatrick Classification of Skin Phototypes I to IV, and in females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II and Fitzpatrick Classification of Skin Phototypes I to IV.	YES
Mode of Operation	Low-level laser diodes and light emitting diodes	Low-level laser diodes and light emitting diodes	YES
Wavelength	655 nm	655 nm	YES

Number of LDs/LEDs	LDs: 21 LEDs: 30	LDs: 21 LEDs: 30	YES
Electrical Requirements	Input: AC 100V ~ 240V (free voltage) Frequency: 50Hz/60Hz Power: 5V 2A	Input: AC 100V ~ 240V (free voltage) Frequency: 50Hz/60Hz Power: 5V 2A	YES
Battery Type	li-on battery	li-on battery	YES
How to use	Helmet system	Helmet system	YES
Treatment time	Each Treatment: 20-25 min Total Treatment: every two days, for 16 weeks	Each Treatment: 20-25 min Total Treatment: every two days, for 16 weeks	YES
Maximum Power	5mW	5mW	YES

6. Performance Data

Non-clinical tests: Measurement of wavelength and average output power, of treatment were performed. Testing conducted on the easy Hairfull shows that it refers to the relevant mandatory performance standards for laser products 21 CFR 1040.10 and 1040.11. Other performance, such as basic safety, etc, were tested using following consensus standards:

- Basic safety and essential performance of the easy Hairfull is tested and evaluated according to IEC 60601-1:2005.
- Effect to the device by electromagnetic disturbances were tested and evaluated according to the FDA-recognized consensus standard, IEC 60601-1-2:2014.
- Safety of laser products is evaluated according to FDA-recognized consensus standard, IEC 60825-1: 2014.
- Photobiological safety of lamps and lamp systems is evaluated according to FDA-recognized consensus standard, IEC 62471:2006.
- Risk management was recorded by referring to ISO 14971:2007.
- Usability was documented referring to IEC 60601-1-6.

7. Substantial Equivalence

The intended use of the easy Hairfull is within the scope of the predicate devices. Easy Hairfull, from both a design and clinical perspective, uses similar or identical technology as the cited predicate devices and has the same intended uses. Based upon the predicted overall performance characteristics for the easy Hairfull, Y&J BIO Co., Ltd. believes that no significant differences exist in usage of its underlying technological principles between easy Hairfull and the cited predicate devices.

8. Conclusions

On the basis of the information provided in this Summary, Y&J BIO Co., Ltd. believes that the easy Hairfull is substantially equivalent to legally commercialized predicate devices for the purposes of this 510 (k) submission.