June 1, 2018

Y&J BIO Co, Ltd.,
Ms. Mina Joo
Assistant Manager
BT Solutions, Inc.
91-14 Seolleung-ri #402
Gangnam-gu, Seoul, 06150 Kr

Re: K180617
Trade/Device Name: Hair Up
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: March 6, 2018
Received: March 8, 2018

Dear Mina Joo:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K180617

Device Name
Hair Up

Indications for Use *(Describe)*
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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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5. 510(k) Summary

1. General Information

Applicant/Submitter:	Y&J BIO Co., Ltd.
Address:	No. C-413, Munjeong Hyundai Knowledge Center 1, 7, Beobwon-ro 11-gil, Songpa-gu, Seoul, Republic of Korea Tel) +82-3400-0325
Contact Person:	Mina Joo, BT Solutions, Inc.
Address:	Unit 402, 91-14 Seolleung-ro, Seoul, Republic of Korea Tel) +82.2.538.9140 Email) smanager@btsolutions.co.kr
Preparation Date:	June-1-2018

2. Device Name and Code

Device Trade Name:	Hair Up
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 (ODE)

3. Predicate Devices

Hair Up is substantially equivalent to the following device

Table 5.1 Primary Predicate device

Applicant	Device Name	510(k) Number
Apira Science Inc.	iGrow-II Hair Growth System	K140931

Table 5.2 References predicate devices

Applicant	Device Name	510(k) Number
Apira Science Inc.	iGrow-II Hair Growth System	K141567
Slinph Technologies Co., Ltd.	iHelmet Hair Growth System	K162782

4. Device Description

The Hair Up is basically an identical device with the 510(k)-cleared device Hair Up (K172968). A new 510(k) clearance is applied this time with a new indications for use (IFU).

Subject device, Hair up and its primary predicate device consist 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 full coverage of the upper 1/3 of the head which is commonly covered with stylized hair. The system will automatically pause therapy until the correct head position is re-established. At the end of the therapy cycle, the subject device Hair Up signals that therapy is complete and the device is ready to be powered down.

5. Indications / 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.

6. Technical Characteristics in Comparison to Predicate Devices

Hair Up is substantially equivalent to the following legally marketed predicate devices

	Primary Predicate Device	**Reference Device 1**	**Reference Device 2**	**Proposed Device**
510(K) Number	K140931	K141567	K162782	Not Available
Manufacturer	Apira Science, Inc.	Apira Science, Inc.	Slinph Technologies Co., Ltd.	Y&J BIO Co., Ltd.
Device Name	iGrow-II Hair Growth System	iGrow-II Hair Growth System	iHelmet Hair Growth System	Hair Up
Clearance Date:	December 5, 2014	August 21, 2014	April 4, 2017	N/A
Classification / Regulation	Class 2 / 890.5500	Class 2 / 890.5500	Class 2 / 890.5500	Class 2 / 890.5500
Product Code	OAP	OAP	OAP	OAP
Intended Use	The iGrow-II Hair Growth System is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II and Fitzpatrick Classification of Skin Phototypes I to IV.	The iGrow-II Hair Growth System is indicated 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.	iHelmet Hair Growth System (Model: LTD200S) 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	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

			Classifications IIa - V and for both, Fitzpatrick Classification of Skin Phototypes of I - IV.	of I-II and Fitzpatrick Classification of Skin Phototypes I to IV.
Mode of Operation	Low-level laser diodes and light emitting diodes	Low-level laser diodes and light emitting diodes	Low-level laser diodes and light emitting diodes	Low-level laser diodes and light emitting diodes
Wavelength	655 nm	655 nm	650 nm±10 nm	655 nm
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	Input: DC 5V, 2A, USB charger; Internal lithium battery Battery Voltage 3.7V Battery Capacity 3000mAh，11.1Wh	Input: AC 100V ~ 240V (free voltage) Frequency: 50Hz/60Hz Power: 5V 2A
How to use	Helmet system	Helmet system	Helmet system	Helmet system
Treatment time	20-25 min	20-25 min	20-35 min	20-25 min

Reference Devices:

1. Apira Science, Inc's iGrow-II Hair Growth System (K141567)*

   *This reference device is referred, of which the technical aspects such as number of diodes, treatment time and intended use for males are same to those of the Hair Up.

2. Slinph Technologies Co., Ltd.'s iHelmet Hair Growth System (K162782) **

   **This reference device is referred, of which the intended use for both males and females is same, the fluence and irradiance are comparable to those of the Hair Up.

6. Performance Data

Non-clinical tests: Measurement of wavelength and average output power, of treatment were performed. Testing conducted on the Hair up 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 Hair Up 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.
- Biological evaluation of medical devices is tested and evaluated according to ISO 10993-5: 2009 and ISO 10993-10:2010.

- Risk management was recorded by referring to ISO 14971:2007.
- Usability was documented referring to IEC 62366.

7. Conclusions

The technological characteristics of the subject device Hair Up are comparable to those of the predicates for comparable indications for use. Thus, subject device Hair Up is concluded to be substantially equivalent to the predicates.