DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Trophy Skin Incorporated
% Mr. Raymond R. Blanche
NST Consulting, LLC
641 Shunpike Road, Suite 311
Chatham, New Jersey 07928

November 16, 2015

Re: K152019
Trade/Device Name: HairMD
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP
Dated: September 24, 2015
Received: October 22, 2015

Dear Mr. Blanche:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152019

Device Name
HairMD

Indications for Use *(Describe)*
The HairMD 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 Ila-V and for both, Fitzpatrick Classification of Skin Phototypes of l-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

Trophy Skin, Inc.

Submitter's Contact Information

Name: Raymond R. Blanche

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641 Shunpike Road, Suite 311
Chatham, NJ 07928

Telephone: (973) 539-7444
Facsimile: (973) 539-7445

Name of Device and Name/Address of Sponsor

Trade Name: HairMD

Sponsor Contact Information:
Imran Karim
Trophy Skin, Inc.
4372 Kenmare Trail
Frisco, Texas 75034
T. 469-233-1768

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 Devices:

Device Trade Name	Manufacturer
iGrow Hair Growth System-K140931	Apira Science, Inc.
iGrow Hair Growth System-K141567	Apira Science, Inc.

Reference Devices:

Hairmax Lasercomb - K142573	Lexington International

Date Prepared: Revised, November 12, 2015

Intended Use / Indications for Use

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

Technological Characteristics

The HairMD consists of 21 red, visible-light, continuous wave diode lasers operating at 650 nanometers and 30 super luminescent light emitting diodes (LEDs), operating at 650 nanometers that are configured within a protective inner liner and outer helmet. The HairMD is physically similar to the iGrow Hair Growth System, except that it does not contain earphones or inner liner spacers. The use of these specific number of diode lasers and LEDs, provides for a full coverage of the upper 1/3 of the head; i.e., the area commonly covered with stylized hair. The helmet system will automatically pause therapy if the subject's head is moved outside of the zone of radiation and will resume therapy when the correct head position is re-established. This is achieved by a safety interlock. At the beginning and end of a therapy session, audible tones are delivered to the user, indicating that therapy has begun (2 beeps) or ended (one long beep). The system is powered by line voltage, operating at 110/220 volts.

Performance Data:

No clinical trial data for the HairMD was submitted for this 510(k). The device was tested for conformance with IEC 60601-1-11 (edition 3.0), and IEC 60825-1 (edition 1.2). The testing results demonstrate that the HairMD device performed safely and effectively and that the device does not raise new types of questions regarding effectiveness or safety when compared to the predicate device.

Substantial Equivalence

The HairMD utilizes the same technological characteristics as the predicate device. The HairMD uses the same pulsing characteristics for its laser diodes and LEDs as the K140931 and K141567 (iGrow Hair Growth System)) device, and provides similar energy and irradiance output to the treatment area as this predicate.

The HairMD is designed to provide low-level-laser therapy. Both the predicate device and the proposed device use red light diode lasers and LEDs operating at the same wavelength of light, 650 nanometers. The sponsor believes that the differences between the subject device of this 510(k) compared with the predicate device, does not substantially affect the therapeutic value or the safety profile. There are differences in the physical appearance of the HairMD compared to the iGrow Hair Growth System. These differences are not significant and do not affect the safety or efficacy profile of the proposed device.

Conclusion

The HairMD utilizes the same technological characteristics as the predicate device listed above, and is to be used for the same intended use. The sponsor believes that there are no new types of safety and effectiveness questions for the HairMD when compared with the predicate device, and therefore that the device should be considered substantially equivalent to the predicate devices.