December 13, 2019

Shang Fa Biotechnology Co.
Chung Ju Zhi
General Manager
B1F., No. 6, Ln. 1, Qingli St., Tucheng Dist.,
New Taipei City, 23677 TW

Re: K192627
Trade/Device Name: Laser Hair Growth Cap
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: September 18, 2019
Received: September 23, 2019

Dear Chung Ju Zhi:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K192627

Device Name
Laser Hair Growth Cap

Indications for Use *(Describe)*
Laser Hair Growth Cap is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V or females with androgenic alopecia who have Ludwig-Savin Classifications of I-II and both with Fitzpatrick 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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K192627

510(k) SUMMARY

5.1 Type of Submission: Traditional

5.2 Date of Summary: 12/12/2019

5.3 Submitter:

Address:	Shang Fa Biotechnology Co. B1F., No. 6, Ln. 1, Qingli St., Tucheng Dist., New Taipei City 23677, Taiwan (R.O.C.)
Phone:	+886-967-001688
Contact:	MS. CHUNG JU ZHI (info@new-hair.net)

5.4 Identification of the Device:

Proprietary/Trade Name:	Laser Hair Growth Cap
Model Number:	TW280, TW272, TW147, TW080
Regulation Description:	Infrared lamp
Review Panel:	General & Plastic Surgery
Regulation Number:	890.5500
Device Class:	II
Product Code:	OAP

5.5 Identification of the Predicate Device:

Predicate Device Name:	Diode Laser Cap
Model Number:	COSMO-030, COSMO-020
Manufacturer:	Cosmo Far East Technology Limited
Regulation Number:	890.5500
Device Class:	II
Product Code:	OAP
510(k) Number:	K173678

Predicate Device Name:	Irradiation Aesthetic Device
Model:	HairPro

Manufacturer:	Chongqing Peninsula Medical Technology Co., Ltd.
Regulation Number:	890.5500
Device Class:	II
Product Code:	OAP
510(k) Number:	K171835

5.6 Intended Use/ Indications for Use of the Device

Laser Hair Growth Cap is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V or females with androgenic alopecia who have Ludwig-Savin Classifications of I-II and both with Fitzpatrick Skin Phototypes I-IV.

5.7 Device Description

Laser Hair Growth Cap is a dome-shaped low level laser therapy (LLLT) device designed to promote hair growth in women and men by exposing the entire scalp to the photobiostimulation of 280, 272, 147, and 80 laser diodes at 650nm and 5mW each. The Cap is designed with an outer plastic cover and a protective inner liner (containing the electronics and laser array) and is powered by an included battery pack.

5.8 Substantial Equivalence Determination

Laser Hair Growth Cap (model number: TW280, TW272, TW147, and TW080) submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation and performance to the cleared *Diode Laser Cap, model number: COSMO-030 and COSMO-020 (K173678)*, and *Irradiation Aesthetic Device, model: HairPro (K171835)*. Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

Item	Subject device	Predicate device I	Predicate device II	Substantial equivalence determination
510(k) No.	K192627	K173678	K171835	N/A
Proprietary name	Laser Hair Growth Cap	Diode Laser Cap	Irradiation Aesthetic Device	
Model number	TW280, TW272, TW147, TW080	COSMO-030, COSMO-020	HairPro	
Intended use	Laser Hair Growth Cap is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V or females with androgenic alopecia who have Ludwig-Savin Classifications of I-II and both with Fitzpatrick Skin Phototypes I-IV.	Diode Laser Cap is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa~V or females with androgenic alopecia who have Ludwig-Savin Classifications of I~II and both with Fitzpatrick Skin Phototypes I to IV.	The Irradiation Aesthetic Device (Model: HairPro) 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.	SE
Type of use	OTC	OTC	OTC	SE
Type of light	Low level laser therapy (LLLT); Laser diodes	Low level laser therapy (LLLT); Laser diodes	Low level laser therapy (LLLT); Laser diodes	SE

Item	Subject device	Predicate device I	Predicate device II	Substantial equivalence determination
Wavelength	650 nm	650 nm	650 nm	SE
Amount of laser diodes	TW280: 280 TW272: 272 TW147: 147 TW080: 80	COSMO-030: 272, COSMO-020: 148	81	SE*
	***SE determination:** **Amount of laser diodes of the subject device can be corresponding to that of the predicate devices. The difference in number of diodes is of no consequence and does not affect safety or efficacy as there is a wide range of number of diodes in the predicate devices listed and in other LLLT devices cleared under product code OAP. Thus, we consider the subject device is substantially equivalent to the predicate devices.**			
Energy of per laser diode	5mW	5mW	5mW	SE
Classification according to IEC60825-1	Class 3R	Class 3R	Class 3R	SE
Treatment time	Each treatment: 30 min; 16 weeks, 3 times per week spaced out every other day	Each treatment: 30 min; 16 weeks, every other day (indefinite)	Each treatment: 30 min; Total treatment: 3 times per week	SE*
	***SE determination:** **All devices have the same treatment time for 30 mins. The subject device recommends the treatment frequency should be 3 times per week spaced out every other day, and that is equal to the frequency of predicates. LLLT device can be used more than 16 weeks under the condition without exceeding every other day for 30 minutes. Therefore, we consider the subject device is substantially equivalent to the predicate devices.**			

Item	Subject device	Predicate device I	Predicate device II	Substantial equivalence determination
Applicable people	Male: Norwood-Hamilton IIa~V Female: Ludwig-Savin I~II	Male: Norwood-Hamilton IIa~V Female: Ludwig-Savin I~II	Male: Norwood-Hamilton IIa~V Female: Ludwig-Savin I~II	SE
Applicable skin	Fitzpatrick Skin Phototypes I-IV	Fitzpatrick Skin Phototypes I-IV	Fitzpatrick Skin Phototypes I-IV	SE
Design	Cap	Cap	Cap	SE
Dimension (L*W*H)	22*18*9 cm	22*18*9 cm	19.9*17.9*8.8 cm	SE*
Weight	TW280: 0.32 kg TW272: 0.30 kg TW147: 0.26 kg TW080: 0.25 kg	0.26 kg	1000g	SE*
Environment for operation	Temperature: 5 ℃~30℃ (41°F~86°F) Humidity: 15%~90%	Temperature: 10 ℃~30℃ (50°F~86°F) Humidity: 20%~80%	Temperature: 5 ℃~30℃ Humidity: ≤80%	SE*
Environment for storage	Temperature: -40 ℃~70℃ (-40°F~158°F) Humidity: 10%~100%	Temperature: -10 ℃~60℃ (14°F~140°F) Humidity: 20%~80%	Temperature: 0°C~50°C Humidity: ≤ 85%	SE*
	***SE determination:** **The above items, "Dimension", "Weight", "Environment for Operation" and "Environment for Storage" of subject device are slightly different from the predicate devices, but it will not affect the main function and the intended use of the device as they all also comply with IEC 60601-1 requirements. Besides, the**			

Item	Subject device	Predicate device I	Predicate device II	Substantial equivalence determination
	subtle changes of the physical characteristics will not affect the critical functions or the normal use. Therefore, we consider the subject device is substantially equivalent to the predicate devices.			
Safety feature	Complied with IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2, IEC 60825-1 Complied with IEC 62133 (Battery pack) Complied with IEC 60950-1 (Adapter)	Complied with IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2, IEC 60825-1 Complied with IEC 62133 (Battery pack) Complied with IEC 60950 (Adapter)	Complied with IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2, IEC 60825-1	SE
Biocompatibility feature	Complied with ISO 10993-5 and ISO 10993-10.	Complied with ISO 10993-5 and ISO 10993-10.	Complied with ISO 10993-5 and ISO 10993-10.	SE

5.9 Similarity and Difference

Laser Hair Growth Cap (model number: TW280, TW272, TW147, and TW080) has been compared with "Diode Laser Cap, model number: COSMO-030 and COSMO-020" and "Irradiation Aesthetic Device, model: HairPro".

The safety and performance tests have been conducted on subject device, and the results complied with the test requests. Testing to IEC 60825-1 certifies the laser system to classification 3R, same as the predicates.

The subject device has the same safety and performance claims, principle of

operation, and similar technological characteristics as the predicate devices. Although there are slight difference on few specifications between the subject device and the predicate devices, after comparison analyzed considering test results, the difference did not raise any problem of substantial equivalence. No new safety or efficacy concerns are raised due to the minor differences present between devices.

5.10 Non-clinical Testing

A series of safety and performance tests were conducted on the subject device, Laser Hair Growth Cap (model number: TW280, TW272, TW147, and TW080).

- Shelf life
- Software validation
- Biocompatibility
  - ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
  - ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
- Electromagnetic compatibility and electrical safety
  - IEC 60601-1:2005+COR.1:2006+COR.2:2007+A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
  - IEC 60601-1-11:2015, Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
  - IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
  - IEC 62133:2012 (Battery pack), Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements

for portable sealed secondary cells, and for batteries made from them, for use in portable applications.

- IEC 60950-1:2005+A1:2009+A2:2013 (Adapter), Information technology equipment - Safety - Part 1: General requirements.

- Performance test
  - IEC 60825-1:2014, Safety of laser products - Part 1: Equipment classification and requirements.
- Usability test
  - IEC 60601-1-6:2010+A1:2013, Medical electrical equipment - Part 1-6: General requirements forbasic safety and essential performance - Collateral standard: Usability.
  - IEC 62366-1:2015, Medical devices - Part 1: Application of usability engineering to medical devices.

All the test results demonstrate Laser Hair Growth Cap (model number: TW280, TW272, TW147, and TW080) meets the requirements of its pre-defined acceptance criteria and intended uses, and is substantially equivalent to the predicate devices.

5.11 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

5.12 Conclusion

After analyzing non-clinical laboratory studies and safety testing data, it can be concluded that Laser Hair Growth Cap (model number: TW280, TW272, TW147, and TW080) is substantially equivalent to the predicate devices.