Xuzhou Kernel Medical Equipment Co., Ltd.
℅ Jet Li
Regulation Manager
Guangzhou KEDA Biological Tech Co., Ltd.
6F, No.1 TianTai road, Science City, LuoGang District
Guangzhou, CN

July 26, 2019

Re: K190685
Trade/Device Name: Hair Growth System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: June 18, 2019
Received: June 28, 2019

Dear Jet Li:

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,

Neil R. P. Ogden, M.S.
Acting Team Assistant Director
Light Based Devices Team
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)*
K190685

Device Name
Hair Growth System Device (Model: KN-8000A)

Indications for Use *(Describe)*
The Hair Growth System (Model: KN-8000A) is a prescription use device intended for the promotion of hair growth in females with androgenic alopecia who have Ludwig-Savin Classifications I- II, and in males with androgenic alopecia who have Norwood Hamilton Classifications IIa-V; and both genders having 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.

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Date of the summary prepared: July 26, 2019

510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

Sponsor

- Company Name: Xuzhou Kernel Medical Equipment Co., Ltd.
- Address: Kernel Mansion, Economic Development District, Xuzhou City, Jiangsu Province, China
- Phone: +86 1831 685 8036
- Fax: +86 0516-87732208 13776587162
- Contact Person (including title): Wang Jing (Management Representative)
- E-mail: wjkernel@126.com

Application Correspondent:

Guangzhou KEDA Biological Tech Co., Ltd.
Address: 6F, No.1 TianTai road, Science City, LuoGang District, GuangZhou City, China
Contact Person: Jet Li
Tel: +86-18588874857
Email: med-jl@foxmail.com

2. Subject Device Information

- Trade Name: Hair Growth System (Model: KN-8000A)
- Common Name: Lamp, non-heating, for promotion of hair growth
- Classification name: Infrared lamp per 21 CFR 890.5500surgery and in dermatology
- Review Panel: General & Plastic Surgery
- Product Code: OAP (Laser, comb, hair)
- Regulation Class: 2
- Regulation Number: 21 CFR 890.5500

3. Predicate Device Information

Sponsor	Capillus, LLC.	Sunetics International Marketing Group LLC
Device Name	Capillus devices	Sunetics Clinical Laser "G"

	Capillus352; Capillus302	
510(k) Number	K162994	K132646
Product Code	OAP	OAP
Regulation Number	21 CFR 890.5500	21 CFR 890.5500
Regulation Class	2	2

2. Device Description

The Hair Growth System Model: KN-8000A is a transportable, non-invasive, low-level laser device intended to treat Androgenetic Alopecia (Hair Loss) and to promote hair growth in both Males and Females. It produces a red light, diode lasers operating at a 650-nanometer wavelength (maximum output power of each is 5 mW). The device mainly includes a host machine, light source and lifting bracket. The light source applicator was equipped with the access sensor device, it can power off the light source when the patient's scalp deviates from the work area.

5. Intended Use / Indications for Use

The Hair Growth System (Model: KN-8000A) is intended for the promotion of hair growth in females with androgenic alopecia who have Ludwig-Savin Classifications I-II, and in males with androgenetic alopecia who have Norwood Hamilton Classifications IIa-V; and both genders having Fitzpatrick Classification of Skin Phototypes I-IV.

6. Design

The Hair Growth System (Model: KN-8000A) is designed to be free to stretch and be able to take care of every part of the scalp in consideration of the characteristics of the human head. The device laser light source is arranged in matrix structure with dot scope to balance the light energy. Light source shall achieve the fixation of light source and connections with electrical through the military-class quick connector, which makes it more convenient and faster to replace the light source. Free lift shall be designed of cantilever, so that the light source can stay at any angle. 8 "rotatable touch screen design, easy to operate, which does not need the professional training. According to the difference of the treatment parts, each treatment hood array can be controlled individually. According to treatment needs, the continuous irradiation or pulse irradiation mode can be selected. There is the function of auxiliary display in the light source, to facilitate doctors to timely grasp the treatment time information. There is the access sensor in the treatment applicator of the hood array. When the patient's scalp deviate from the work area, the light source can be stopped in time to ensure patient safety. Working distance positioning equipment, to facilitate users to quickly adjust to the appropriate working distance. Double switch protections of key switch and power-on password, to prevent the use of unauthorized personnel.

7. Materials

There is one kind of patient- directly contacting component in the subject device as the following list.

Component of Device Requiring Biocompatibility	**Material of Component**	**Body Contact Category (ISO 10993-1)**	**Contact Duration (ISO 10993-1)**
loop bar sucker	silicon rubber	Surface-contacting device: skin of patient head	Maximum 30 minutes(< 24hours)

We conduct biocompatibility test on the material of loop bar sucker. So the parts' biocompatibility is safe.

8. Physical characteristics

Basic Unit Characteristics	
Compliance* with 21 CFR 898	No
Main Unit Weight	3.0-4.0 kg
Housing Materials of main unit	ABS
Environment for operation	Temperature: 5 ~ 40 ℃ Relative humidity: ≤85% Atmospheric pressure: 700hPa ~ 1060hPa
Storage and Transport Conditions	Temperature: -5 ~ 40 ℃ Relative humidity: 10-95% Atmospheric pressure: 700hPa ~ 1060hPa
Compliance with Voluntary Standards	Yes, Comply with IEC 60601-1, IEC 60601-1-2, IEC 60825-1
Patient leakage current	Comply with IEC 60601-1
Power Source	AC 100-240V, 50 / 60Hz ± 2%
Software/Firmware/Microprocessor Control?	Yes
Specification	
Input power	120VA
The specification and rating value of fuse protector	T1.5AL / 250V Φ5 * 20
Structure style of stand	Cart type
Radiation area	900 cm^2±10%
Irradiation distance	4cm±1cm
Laser Category	3R laser products
Laser output wavelength	650nm±10nm
Maximum output laser radiation	＜5mW
Technology	Laser

10. Test Summary

The Hair Growth System has been evaluated for its safety and performance by lab bench testing as following:

- Electrical safety test according to IEC 60601-1 and IEC 60825-1 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 standard
- Software verification and validation test according to the requirements of the FDA "Guidance for PreMarket Submissions and for Software Contained in Medical Devices"

11. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, and intended use of Hair Growth System, model: KN-8000A is substantially equivalent to the predicate devices quoted above.

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	**Subject Device**	**Predicate Device I**	**Predicate Device II**
510(k) Number	Candidate	K162994	K132646
Device Name	Hair Growth System	Capillus Devices Capillus352; Capillus302	Sunetics Clinical Laser "G"
LLLT Device Type	LLLT	LLLT	LLLT
Prescription	Prescription Use	Prescription Use	Prescription Use
Intended Use	intended for the promotion of hair growth in females with androgenic alopecia who have Ludwig-Savin Classifications I-II, and in males with androgenetic alopecia who have Norwood Hamilton Classifications IIa-V; and both genders having Fitzpatrick Classification of Skin Phototypes I-IV.	intended to treat Androgenetic Alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of IIa to V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig (Savin) Scale I-1 to I-4, II-1, II-2, or frontal; both with Fitzpatrick Skin Types I to IV.	The Sunetics Clinical Laser (model 'G" & model "W2326") is indicated to treat Androgenetic Alopecia (Hair Loss) and to promote hair growth in Males who have Norwood Hamilton Classifications of IIa to V and Fitzpatrick Skin Types I to IV and also in Females who have Ludwig (Savin) 1-4.11I-1, 11-2, or frontal patterns of hair loss & Fitzpatrick Skin Types I to IV.
Laser Diode Class	3R	3R	3R
Design	Hood array	Helmet/Cap	Hood array
Laser Diode Power	4.5mW±10%	5mW max	5mW max
Wavelength	650nm	650nm	650nm
Irradiance (power per area)	2.332mW/cm2	Capillus352: 2.745 mW/cm^2 Capillus302: 2.256 mW/cm^2	-
Classification	OAP	OAP	OAP
Classification Name	Infrared Lamp	Infrared Lamp	Infrared Lamp
Common Usage Name	Lamp, Non-Heating	Lamp, Non-Heating	Lamp, Non-Heating
Review Panel	General & Plastic Surgery Committee	General & Plastic Surgery Committee	General & Plastic Surgery Committee

Elements of Comparison	Subject Device	Predicate Device I	Predicate Device II
Fitzpatrick Skin Phototypes	I- IV	I- IV	I- IV
Ludwig-Savin Scale (women)	Ludwig-Savin I-II (females)	Ludwig-Savin I-II (females)	Ludwig-Savin I-II (females)
Norwood-Hamilton (men)	Norwood Hamilton IIA-V (males)	Norwood Hamilton IIA-V (males)	Norwood Hamilton IIA-V (males)
Treatment Frequency	Treatment- 17weeks, every other day (indefinite)	Treatment- 17weeks, every other day (indefinite)	every other day (indefinite)
Device Class	II	II	II
Biocompatibility	ISO 10993-5; ISO10993-10	ISO 10993-5; ISO10993-10	ISO 10993-5; ISO10993-10
Safety and EMC standard	IEC 60601-1; IEC60601-1-2	IEC 60601-1; IEC60601-1-2	IEC 60601-1; IEC60601-1-2
Laser performance standard	IEC60825-1	IEC60825-1	IEC60825-1