June 3, 2020

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, Guangdong
China

Re: K200929
Trade/Device Name: Hair Growth System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: March 15, 2020
Received: April 7, 2020

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 and Part 809); 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,

Colin Kejing Chen, Ph.D.
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)*
K200929

Device Name
Hair Growth System (Model: KN-8000B/KN-8000C/KN-8000D/KN-8000E)

Indications for Use *(Describe)*
The Hair Growth System (Model: KN-8000B/KN-8000C/KN-8000D/KN-8000E) 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.

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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Date of the summary prepared: May 30, 2020

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. This is a traditional 510(K) submission with no previous application.

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:

- Company Name: 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-8000B/KN-8000C/KN-8000D/KN-8000E

Data / Model	LD Quantity	LED Quantity
KN-8000B	204	--
KN-8000C	80	30
KN-8000D	21	30
KN-8000E	81	--

- Common Name: Lamp, non-heating, for promotion of hair growth
- Classification name: Infrared lamp
- Review Panel: General & Plastic Surgery

- Product Code: OAP (Laser, comb, hair)
- Regulation Class: 2
- Regulation Number: 21 CFR 890.5500

3. Predicate Device Information

- Predicate Devices for KN-8000B and KN-8000E

	Predicate I	**Predicate II**
Sponsor	DermaScalp LLC	Capillus LLC
Device Name	DermaScalp Laser Cap	Capillus 82, Capillus 202, Capillus 272 Pro, 272 Office Pro, Capillus 302, Capillus 312, and Capillus 352
510(k) Number	K173846	K163170
Product Code	OAP	OAP
Regulation Number	21 CFR 890.5500	21 CFR 890.5500
Regulation Class	2	2

- Predicate Devices for KN-8000C and KN-8000D

	Predicate I	**Predicate II**
Sponsor	Freedom Laser Therapy, Inc.	Freedom Laser Therapy, Inc.
Device Name	iRestore Hair Growth System	iRestore Professional 282
510(k) Number	K151662	K183417
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-8000B/KN-8000C/KN-8000D/KN-8000E) is hands-free, portable, non-invasive, low-level laser device, which consists of red visible light diode lasers and/or LEDs, to produce red light operating at 650nm wavelength (maximum output power of each is 5mW). The laser sources are arranged in a dot matrix arrangement in the inner of the helmet, which could take into account of every hair follicle and promote rapid hair growth. The device will automatically pause therapy if the user's head is moved outside of the zone of radiation and will resume therapy when the correct head position is re-established.

The device could be powered by internal rechargeable li-on battery (Rated 7.2Vd.c. 2100mAh), and it can also be supplied by specified external adapter with rated Input 100-240Vac. 50/60Hz and rated Output 9Vdc 3A.

For KN-8000D and KN-8000E, the device emits an audible voice prompt when the treatment is going to start/pause/end, and the device is going to shut down.

3. Intended Use / Indications for Use

The Hair Growth System (Model: KN-8000B/KN-8000C/KN-8000D/KN-8000E) 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.

4. Test Summary

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

- Electrical safety and performance test according to IEC 60601-1, IEC 60825-1, IEC 62471 and IEC 60601-2-57 standard
- Electromagnetic compatibility test according to IEC 60601-1-2 standard
- Biocompatibility test according to ISO 10993-5 and ISO 10993-10 standard
- Usability test according to IEC 62366
- Software verification and validation test according to the requirements of the FDA "Guidance for Premarket Submissions and for Software Contained in Medical Devices"

5. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, and intended use of Hair Growth System, model: KN-8000B/KN-8000C/KN-8000D/KN-8000E 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.

Substantial Equivalence Comparison Table for KN-8000B/KN-8000E				
Elements of Comparison	**Subject Device**	**Predicate Device I**	**Predicate Device II**	**Verdict**
510(k) Number	TBD	K173846	K163170	--
Device Name	Hair Growth System KN-8000B/ KN-8000E	DermaScalp Laser Cap	Capillus 82, Capillus 202, Capillus 272 Pro, 272 Office Pro, Capillus 302, Capillus 312, and Capillus 352	--
Product Code	OAP	OAP	OAP	SE
Regulation Number	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500	SE
Regulation Class	2	2	2	SE
LLLT Device Type	LLLT	LLLT	LLLT	SE
Prescription	OTC	OTC	OTC	SE
Intended Use	The Hair Growth System (Model: KN-8000B/KN-8000C/KN-8000D/KN-8000E) 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.	The family of DermaScalp Laser Cap devices are indicated to treat Androgenetic Alpopecia 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 Capillus laser domes 82, 202, 272 Pro, 272 OfficePro, 302, 312, and 352, are 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.	SE Minor difference
Waveform	Visible red laser	Visible red laser	Visible red laser	SE
Wavelength	655nm±5nm	650nm	650nm	SE Note 1
Amounts of laser diode	KN-8000B: 204 KN-8000E: 81	50, 80, 120, 148, 180, 202, 224, 272	82, 202, 272, 302, 312, 352	SE Note 2
Laser radiation output	≤5mW	＜5mW	≤5mW	SE Note 1
Classification according to IEC60825-1	Class 3R	Class 3R	Class 3R	SE

Substantial Equivalence Comparison Table for KN-8000B/KN-8000E				
Elements of Comparison	**Subject Device**	**Predicate Device I**	**Predicate Device II**	**Verdict**
Treatment	Each Treatment: 25-35min, Total Treatment: every other day	17weeks, every other day (indefinite)	17weeks, every other day (indefinite)	SE Note 2
Total laser irradiance	KN-8000B: ≤1,020mW KN-8000E: ≤405mW	Diode 50: <250mW, Diode 80: <400mW, Diode 120: <600mW, Diode 148: <740mW, Diode 180: <900mW, Diode 202: <1,010mW, Diode 224: <1,120mW, Diode 272: <1,360mW	Diode 82: <410mW, Diode 202: <1,010mW, Diode 272: <1,360mW, Diode 302: <1,510mW, Diode 312: <1,560mW, Diode 352: <1,760mW	SE Note 2
Appearance Design	Helmet cap	Cap	Cap	SE Minor difference
Safety and Performance Feature	Complied with IEC 60601-1, IEC 60601-1-2, IEC 60825-1	Complied with IEC 60601-1, IEC 60601-1-2, IEC 60825-1, IEC 60601-1-11	Complied with IEC 60601-1, IEC 60601-1-2, IEC 60825-1	SE Note 3
Biocompatibility	All patient contacting materials are complied with ISO 10993-5, ISO 10993-10	All patient contacting materials are complied with ISO 10993-1, ISO 10993-5	All patient contacting materials are complied with ISO 10993-5, ISO 10993-10	SE Note 3

Substantial Equivalence Comparison Table for KN-8000C/KN-8000D				
Elements of Comparison	**Subject Device**	**Predicate Device I**	**Predicate Device II**	**Verdict**
510(k) Number	TBD	K151662	K183417	--
Device Name	Hair Growth System	iRestore Hair Growth System	iRestore Professional 282	--

Substantial Equivalence Comparison Table for KN-8000C/KN-8000D				
Elements of Comparison	**Subject Device**	**Predicate Device I**	**Predicate Device II**	**Verdict**
	KN-8000C/ KN-8000D			
Product Code	OAP	OAP	OAP	SE
Regulation Number	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500	SE
Regulation Class	2	2	2	SE
LLLT Device Type	LLLT	LLLT	LLLT	SE
Prescription	OTC	OTC	OTC	SE
Intended Use	The Hair Growth System (Model: KN-8000B/KN-8000C/KN-8000D/KN-8000E) 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.	The iRestore Hair Growth System is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications of I – II, males who have Norwood-Hamilton Classifications of IIa – V and for both, Fitzpatrick Classification of Skin Phototypes I to IV.	The iRestore Professional 282 is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II, males who have Norwood-Hamilton Classifications of IIa-V and for both, Fitzpatrick Classification of Skin Phototypes I to IV.	SE
Waveform	Visible red laser and light	Visible red laser and light	Visible red laser and light	SE
Wavelength	LD: 655nm±5nm LED: 655nm±20nm	655nm	650nm±10nm	SE Note 1
Amounts of LED	KN-8000C: 30 KN-8000D: 30	30	200	SE Note 2
Amounts of laser diode	KN-8000C: 80 KN-8000D: 21	21	82	SE Note 2
Classification according to IEC60825-1	Class 3R	Class 3R	Class 3R	SE
Treatment time	Each Treatment: 25-35min Total Treatment: every other day	Each Treatment: 25min Total Treatment: every other day, on non-consecutive days, for 16weeks	Each Treatment: 25min Total Treatment: every other day, on non-consecutive days, for 16weeks	SE Note 2
Appearance Design	Helmet cap	Helmet	Helmet	SE

Substantial Equivalence Comparison Table for KN-8000C/KN-8000D				
Elements of Comparison	**Subject Device**	**Predicate Device I**	**Predicate Device II**	**Verdict**
Safety and Performance Feature	Complied with IEC 60601-1, IEC 60601-1-2, IEC 60825-1, IEC 62471, IEC 60601-2-57	Complied with IEC 60601-1, IEC 60601-1-2, IEC 60825-1, IEC 60601-1-11	Complied with IEC 60601-1, IEC 60601-1-2, IEC 60825-1, IEC 60601-1-11	SE Note 3
Biocompatibility	All patient contacting materials are complied with ISO 10993-5, ISO 10993-10	All patient contacting materials are complied with ISO 10993-5, ISO 10993-10	All patient contacting materials are complied with ISO 10993-5, ISO 10993-10	SE

Comparison in Detail(s):

Note 1:

Although the Wavelength and Laser radiation output of subject device have a little difference to the predicate devices, these parameters are similar to the predicate devices, and these minor difference of wavelength will not affect the main function. So the differences will not raise any safety or effectiveness issue.

Note 2:

Although the Amounts of LED and/or laser diode/Treatment Time/Total Irradiance of subject device and predicate devices are a little difference, the energy and power parameters' range of subject device can be covered by predicate device's several models' range; they are very similar. So these parameters' differences will not raise any safety or effectiveness issue.

Note 3:

Although the accepted FDA recognized standards of subject device are a little different from the predicate devices, they all comply with IEC 60101-1/IEC 60601-1-2/IEC 60825, and the subject device also complies with IEC 62471 requirements, so these differences will not affect the critical functions or the normal use.

6. Summary for clinical test

Clinical performance is not deemed necessary.

7. Conclusion

The subject device Hair Growth System (KN-8000B/KN-8000C/KN-8000D/KN-8000E) has all features of the predicate devices for intended use. Thus, the subject device is substantially equivalent to the predicate devices.