DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 3, 2017

Oriental Inspiration Limited
Andy Wu
Director
Unit 607, The Lakeside 2, West Wing, No. 10
Science Park West Avenue
Hong Kong, CN

Re: K170269
Trade/Device Name: Hee Hr Mini
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: OHT
Dated: October 17, 2016
Received: January 27, 2017

Dear Andy Wu:

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" (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 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,

Jennifer R. Stevenson -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)*
K170269

Device Name
HEE HR Mini

Indications for Use *(Describe)*
HEE HR Mini is an over-the-counter device intended for the removal of unwanted hair. The HEE HR Mini is also intended for permanent reduction in hair regrowth, defined as a long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of treatment regimen.

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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Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Traditional 510(k) section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 21 CFR 807.92

1. Submitter of 510(K):

Company Name:	Oriental Inspiration Limited
Address:	Unit 607, The Lakeside 2, West Wing, No. 10 Science Park West Avenue, Hong Kong Science Park, Shatin, N.T. Hong Kong.
Contact person:	Mr. Andy Wu
TEL:	+(852) 2687 3496
FAX:	+(852) 2687 4148
E-mail:	andy_wu@netop.com.hk
Date of Prepared:	10/20/2016

2. Proposed Device and code:

Device Trade Name:	HEE HR Mini
Regulation Medical Specialty	General & Plastic Surgery
Product Code:	OHT
Regulation number	878.4810
Device Class	2

3. Predicate Device:

510(K)	Trade or Proprietary or Model Name	Manufacturer
K140381	sensiLight (sensiLight and sensiLight Plus)	EL Global Trade Ltd.
K141242	Glide device	Home skinovations Ltd

4. Description of Proposed Device:

The HEE HR Mini devices are pulsed light hair removal device. Light-based hair removal is based on the theory of selective photothermolysis in which optical energy is used to disable hair growth. The HR Mini devices are composed of a hand held applicator and an external power supply. The spot size (treatment area) in the HR Mini devices is 3 cm^2. The device contains a lamp, a skin proximity

sensor and a skin color sensor to detect appropriate skin tones. If the HR Mini is not properly applied (in full contact with the skin) or user skin tone is too dark/tanned, the HR Mini will not trigger a pulse.

The device has an on/off button, skin color sensor, light exit window, flash button, led indicator, two intensity button, socket for battery charging.

5. Intended for Use

HEE HR Mini is an over-the-counter device intended for the removal of unwanted hair. The HEE HR Mini is also intended for permanent reduction in hair regrowth, defined as a long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of treatment regimen.

6. Technical and Performance

The following table compares the device to the predicate device with basic technological characteristics.

Parameter	New device	Predicate device	Predicate device	Remark
510(k) Number	(to be assigned)	K140381	K141242	--
Device Name and Model	HEE HR Mini	sensiLight (sensiLight and sensiLight Plus)	Glide device	--
Manufacturer	Oriental Inspiration Limited	EL Global Trade Ltd.	Home skinovations Ltd	--
Regulation Number	878.4810	878.4810	878.4810	SE
Intend of use	HEE HR Mini is an over-the-counter device intended for the removal of unwanted hair. The HEE HR Mini is also intended for permanent reduction in hair regrowth, defined as a long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of treatment regimen.	The sensiLight is an over the counter device intended for the removal of unwanted hair. The sensiLight is also intended for permanent reduction in hair regrowth, defined as a long-term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of treatment regimen.	The Glide device is an over the counter device intended for the removal o unwanted hair. The Glide device is also intended for permanent reduction in hair regrowth, defined as a long-term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months afte the completion of treatment regimen.	SE
Operation	Photothermolysis. Light	Photothermolysis. Light	Photothermolysis. Light	SE

Principle	energy is absorbed, heats the hair follicles and interrupts the growth cycle.	energy is absorbed, heats the hair follicles and interrupts the growth cycle.	energy is absorbed, heats the hair follicles and interrupts the growth cycle.	
Technology	Home Pulsed Light	Home Pulsed Light	Home Pulsed Light	SE
Comparison of treatment regime	• The 1–4 treatments will be approximately two weeks apart • Followed by 5-7 treatments plan four week time intervals. • Treatments 8 and after: Treat as needed until decided results are achieved	• The 1–4 treatments will be approximately two weeks apart • Followed by 5-7 treatments plan four week time intervals. • Maintenance will be needed from time to time if growth is still visible	• The 1–4 treatments will be approximately two weeks apart • Followed by 5-7 treatments plan four week time intervals. • Treatments 8 and after: Treat as needed until decided results are achieved	SE
Safety	IEC 60601-1:2005 IEC 60601-1-11:2010 IEC 60601-2-57:2011 IEC 62471:2006 IEC 60601-1-2:2013	IEC 60601-1:2005 IEC 60601-1-11:2010 IEC 60601-2-57:2011 IEC 62471:2006 IEC 60601-1-2:2013	IEC 60601-1:2005 IEC 60601-2-57:2011 IEC 60601-1-2:2013 IEC 62471:2006	SE
Performance Features				
Optical aperture	3 [cm^2]	3 [cm^2]	2.7 [cm^2]	Same as K140381, and different with K141242, Note 1
Emitted Spectrum	475-1200 [nm]	475-1200 [nm]	475-1200 [nm]	SE
Max energy level (fluence)	5 [joules/cm^2]	5 [joules/cm^2]	5 [joules/cm^2]	SE
User selectable Energy levels	8	3	5	Different with K141242, and K140381, Note 1
Single pulse duration	500-800 [uSec]	500-800 [uSec]	500-800 [uSec]	SE
Use Classification	OTC	OTC	OTC	SE
Power Supply	External power supply	External power supply	External power supply	SE

	100-240 VAC, 50-60Hz 0.8A	110-240 VAC, 50-60Hz to 19VDC, 1.8A	100-240 VAC, 50-60Hz 2A	Note 1
Safety Features				
Close contact detector	Prevent the activation of the device while not in close contact with the skin.	Prevent the activation of the device while not in close contact with the skin.	Prevent the activation of the device while not in close contact with the skin.	SE
Pigmentation level detector	Optical – does not allow activation on dark skin	Optical – does not allow activation on dark skin	Optical – does not allow activation on dark skin	SE
Darkest skin allowed	Fitzpatrick 4	Fitzpatrick 4	Fitzpatrick 4	SE
Materials	Top, Side and Bottom shell - ABS/PC plastic (Acrylonitrile butadiene styrene/PolyCarbonate) Optical Filter - Color glass which purpose is of an optical long pass filter tested for biocompatibility	Top, Side and Bottom shell - ABS/PC plastic (Acrylonitrile butadiene styrene/PolyCarbonate) Optical Filter - Color glass which purpose is of an optical long pass filter tested for biocompatibility	Device outer body - ABS/PC plastic (Acrylonitrile butadiene styrene/PolyCarbonate) Optical Filter - Color glass which purpose is of an optical long pass filter tested for biocompatibility	SE
Overall Design	The HEE HR Mini device is light based hair removal system composed of a hand-held applicator.	The sensiLight device is light based hair removal system composed of a hand-held applicator.	The Glide device is light based hair removal system composed of a hand held applicator.	SE

Note 1

Although it is a little different from the predicate devices, it will not affect the main function and the intended use of the device. They all also comply with safety and performance requirements. So the differences will not raise any safety or effectiveness issue.

7. PERFORMANCE DATA

The testing for HEE HR Mini included performance, software, electrical safety, EMC, biocompatibility and bench. HEE HR Mini passed all testing in support of the substantial equivalence determination:

7.1. Biocompatibility testing

The biocompatibility evaluation for the HEE HR Mini was conducted in accordance with International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation

and Testing Within a Risk Management Process." As dictated by the application and duration of contact with the intact skin, the enclosure of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

7.2. Electrical safety and electromagnetic compatibility

Electrical safety, performance and EMC testing were conducted on the HEE HR Mini. The device with compliance with the IEC 60601-1, IEC 60601-1-11, IEC 60601-2-57 and IEC 62471 standards for safety and the IEC 60601-1-2 standard for EMC.

7.3. Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern.

8. Conclusions:

The proposed device has the same intended use and similar characteristics as the predicate device, the sensiLight (sensiLight and sensiLight Plus) (K140381) and Glide device (K141242). Meanwhile, performance testing, bench testing, and safety report documentation supplied in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness.

Based on performance testing, the proposed device is Substantially Equivalent (SE) to the predicate device.