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

March 2, 2017

Beijing Honkon Technologies Co., Ltd
% Ray Wang
General Manager
Beijing Believe Technology Service Co., Ltd.
5-1206, Build 332, DaFangJu, No.25 BanBiDian Rd.
LiYuan Town, TongZhou District
Beijing, 101121 CN

Re: K161892
Trade/Device Name: Slimming Treatment Device
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: NUV, ISA
Dated: January 18, 2017
Received: January 23, 2017

Dear Mr. Wang:

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)*

K161892

Device Name
Slimming Treatment Device

Indications for Use *(Describe)*

The HONKON-Slimming I+/HONKON-Slimming III+ are indicated for the relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation, temporary reduction in the appearance of cellulite, and for temporary reduction of thighs circumferences.

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

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K161892

1. Date of Preparation: 03/01/2017

2. Sponsor Identification

BEIJING HONKON TECHNOLOGIES CO., LTD

72 building, 16#Huanke middle road, Golden bridge scientific and technological industry base Tongzhou Yard, Zhongguan village technological Yard, Tongzhou district, Beijing, China.

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Slimming Treatment Device
Common Name: Massager, Vacuum, Light Induced Heating.
Model(s): HONKON-Slimming I+、HONKON-Slimming III+

Regulatory Information:
Classification Name:
Laser surgical instrument for use in general and plastic surgery and in dermatology；
Classification: II;
Product Code: NUV、ISA;
Regulation Number: 21 CFR 878.4810；
Review Panel: General & Plastic Surgery;

Intended Use Statement:
The HONKON-Slimming I+/HONKON-Slimming III+ are indicated for the relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation,temporary reduction in the appearance of cellulite, and for temporary reduction of thighs circumferences.

Device Description:
The HONKON-Slimming I+ and HONKON-Slimming III+ are the non-invasive body shaping product to combine four different technologies including IR (infrared), Bi-Polar RF (radio-frequency) and mechanical tissue manipulation using pulsed vacuum and massage rollers. The combination of the IR and vacuum coupled RF technologies causes deep heating of the connective tissue including the fibrous septae which in turn promotes an increase in local cellular reduction. The additional mechanical tissue manipulation of the device causes an immediate increase in circulation and lymphatic drainage, both essential components for healthy skin structure.

The HONKON-Slimming I+ and HONKON-Slimming III+ can output infrared light with wavelength 700-2000nm, the infrared light can penetrate whole skin tissue. The infrared light has the effect to expand blood vessels, temporary improvement of local blood circulation; At the same time, this spectrum has a good efficacy for temporary reduction in the appearance of cellulite, and for temporary reduction of thighs circumferences..

The HONKON-Slimming I+ and HONKON-Slimming III+ can output 1MHz frequency, produce RF energy from X, Y and Z directions in the subcutaneous tissue. Temperature of skin tissues becomes higher, Enzyme activity was enhanced so that fat cells can be fully released within the triglyceride；Triglycerides in the fat under the action of enzymes, cracking into fatty acids and

glycerol.

Massage rollers has obvious mechanical compression to skin tissues. Meanwhile, deep negative pressure gives skin and muscles full relaxation and rest. Maximum 8kg negative pressure can absorb all skin tissues into the gap between the bipolar RF tips, ensure RF energy can reach fat layers.

Based on this,the HONKON-Slimming I+/HONKON-Slimming III+ are indicated for the relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation, temporary reduction in the appearance of cellulite, and for temporary reduction of thighs circumferences..

5. Identification of Predicate Device(s)

Predicate Device I :
510(k) Number: K090221
Predicate Device Name: Reaction™ System
Manufacturer: Viora Ltd.

Predicate Device II :
510(k) Number: K122579
Predicate Device Name: VelaShape
Manufacturer: Syneron Medical Ltd.

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

a)IEC 60601-1-2:2007, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests.

b)IEC 60601-1:2005/A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

c)IEC60601-2-2:2009+C1:2014,Medical Electrical Equipment - Part 2-2: Particular Requirements for The Basic Safety And Essential Performance Of High Frequency Surgical Equipment And High Frequency Surgical Accessories [Including: Technical Corrigendum 1 (2014)]

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	Proposed Device HONKON-Slimming I+ HONKON-SlimmingIII+	Predicate Device Reaction™ system (K090221)	Predicate Device VelaShape （K122579）	Remark
Product Code	NUV、ISA	NUV、ISA	NUV	SE
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	SE
Class	II	II	II	SE
Intended Use	The HONKON-Slimming I+/HONKON-Slimming III+ are indicated for the relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation, temporary reduction in the appearance of cellulite, and for temporary reduction of thighs circumferences.	The Reaction ™ system is intended for the treatment of the following medical conditions, using the B-contour and F-contour applicators for delivering non thermal RF combined with massage: - relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement. Of local blood circulation,and - temporary reduction in the appearance of cellulite. Using the ST applicator for delivering RF, the Reaction™ system is intended for the treatment of relief of minor muscle aches and pain.relief of.muscle spasm, temporary improvement of local blood circulation.	The VelaShape is indicated for the relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation, temporary reduction in the appearance of cellulite, and for temporary reduction of thighs circumferences.	SE

Table 2 Performance Comparison

ITEM	Proposed Device HONKON-SlimmingI+ HONKON-SlimmingIII+	Predicate Device Reaction™ system (K090221)	Predicate Device VelaShape （K122579）	Remark
RF Output Energy	40-400W	Up to 50w	Up to 150W	Discussion (a)
RF Output Frequency	1MHz	0.8 MHz, 1.7 MHz, 2.45 MHz	N.A	SE
Max. RF output energy density	XF-I+:12.14W/ cm2 XF-VII+:27W/cm2	78.125W/cm2 4.76W/cm2 33.33W/cm2	115.38W/cm2 6.67W/cm2 12 W/cm2 9.38W/cm2	SE
Infrared energy	XF-I+ & XF-VII+： I: 5W II : 7W III : 8W IV : 9W V :10W	N.A	Up to 3.3W	Discussion (b)
Infrared wavelengths	700-2000nm	N.A.	850nm	SE
Max. IR output energy density	XF-I+:0.30W/cm2 XF-VII+:0.67W/cm2	/	2.54W/cm2 0.44W/cm2 0.26W/cm2 0.21W/cm2	SE
Vacuum	Pulsed (-0.08Mpa－-0.01Mpa)	Pulsed	Pulsed	SE
Mechanical Massage	Yes	Yes	N.A.	SE
Treatment Area	XF-I+: 3294 mm^2 XF-VII+: 1482mm^2	64 mm^2 1050 mm^2 150 mm^2	VContour Applicator: Small Cover Medium Cover Large Cover： 130 mm^2 750 mm^2 1250 mm^2 VSmooth Applicator： 1600 mm^2	Discussion (c)
Weight	48KG	17kg. – desktop 19 kg. – wheel base	20kg / 44lbs	Discussion (d)
Size（mm） L*W*H	434mm * 531mm *1354mm (Slimming I+) 531mm * 441mm *1716mm (Slimming III+)	400*350* 450	380* 490 *1320	Discussion (e)

Table 3 Safety Comparison

ITEM	Proposed Device HONKON-Slimming I+ HONKON-SlimmingIII+	Predicate Device Reaction™ system (K090221)	Predicate Device VelaShape（K122579）	Remark
Power supply	110V, 60HZ	90-264 VAC; 50/60 Hz; Single Phase	110VA; 50Hz; single phase	SE
Electrical Safety	The proposed devices were tested to demonstrated to comply with IEC 60601-1	The proposed devices were tested to demonstrated to comply with IEC 60601-1	The proposed devices were tested to demonstrated to comply with IEC 60601-1	SE
EMC	The proposed devices were tested to demonstrated to comply with IEC 60601-1-2	The proposed devices were tested to demonstrated to comply with IEC 60601-1-2	The proposed devices were tested to demonstrated to comply with IEC 60601-1-2	SE
Patient Contact Material	Handpiece Suction roller	Handpiece Suction roller	Handpiece Suction roller	SE
Biocompatibility				
Cytotoxicity	No toxicity (ISO 10993-5)	No toxicity (ISO 10993-5)	No toxicity (ISO 10993-5)	SE
Irritation	Applied sample did not induce irritation to skin. (ISO 10993-10)	Applied sample did not induce irritation to skin. (ISO 10993-10)	Applied sample did not induce irritation to skin. (ISO 10993-10)	SE
Sensitization	The test article showed no signification evidence of causing skin sensitization in the guinea pig .(ISO 10993-10)	The test article showed no signification evidence of causing skin sensitization in the guinea pig .(ISO 10993-10)	The test article showed no signification evidence of causing skin sensitization in the guinea pig .(ISO 10993-10)	SE

Discussion:

The proposed device has the following differences with the predicate device:

a. RF Output Energy, base on the nonclinical tests (IEC 60601-2-2) performed, the proposed device is as safe, as effective, and performs as well as the predicated device.
b. Infrared energy, base on the nonclinical tests (IEC 60601-1) performed for the risk of heat, the proposed device is as safe, as effective, and performs as well as the predicated device.

c. Treatment Area, which only affect the treatment area's size, no concerned with safety and effective, the proposed device is as safe, as effective, and performs as well as the predicated device.
d. Weight, base on the nonclinical tests (IEC 60601-1) performed for the risk of mechanical, the proposed device is as safe, as effective, and performs as well as the predicated device.
e. Size, base on the nonclinical tests (IEC 60601-1) performed for the risk of mechanical, the proposed device is as safe, as effective, and performs as well as the predicated device.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.