K214015

Heat In A Click LLC.
% Cassie Lee
Official Correspondent
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road,
Huangpu District
Guangzhou, Guangdong 510000
China

Re: K214015
Trade/Device Name: Palm NRG cellulite body device (model: Palm NRG body device)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: August 24, 2022
Received: August 25, 2022

Dear Cassie Lee:

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,

for

Long Chen, Ph.D.
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: 06/30/2023
See PRA Statement below.

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

Device Name
Palm NRG cellulite body device (model: Palm NRG body device)

Indications for Use *(Describe)*
Palm NRG cellulite body device (model: Palm NRG body device) is intended for delivering non thermal RF combined with massage for temporary reduction in the appearance of cellulite.

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) Number: K214015

Sponsor: Heat In A Click LLC

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. Date of the summary updated: 2022-09-24

2. Submitter's Information

510(k) Owner's Name: Heat In A Click LLC

Establishment Registration Number: 3008929787

Address: 1975 Tigertail Blvd Dania FL 33034 USA

Tel: 1(954)518-9777

Fax: 1(954)320-7984

Contact Person: Guy Levi (CEO)

Email: palmnrg@gmail.com

Application Correspondent:

Contact Person: Cassie Lee

Guangzhou GLOMED Biological Technology Co., Ltd.

Address: 2231, Building 1, Rui Feng Center, Kaichuang Road, Huangpu District, Guangzhou, Guangdong, China

Tel: +86 20 8266 2446

Email: regulatory@glomed-info.com

3. Subject Device Information

Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories

Trade Name: Palm NRG cellulite body device

Model Name: Palm NRG body device

Review Panel: General and Plastic Surgery

Product Code: PBX, GEI

Regulation Number: 21 CFR 878.4400

510(k) Number:	K214015
Sponsor:	Heat In A Click LLC

Regulatory Class: II

4.Predicate Device Information

Predicate Device 1:

Sponsor: Heat In A Click LLC

Trade Name: Palm NRG cellulite body device

Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories

510(K) Number: K191940

Review Panel: General and Plastic Surgery

Product Code: PBX, GEI

Regulation Number: 21 CFR 878.4400

Regulation Class: II

Predicate Device 2:

Sponsor: El Global Trade Ltd.

Trade Name: sensiFirm

Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories

510(K) Number: K170637

Review Panel: General and Plastic Surgery

Product Code: PBX, GEI

Regulation Number: 21 CFR 878.4400

Regulation Class: II

5.Device Description

Palm NRG cellulite body device (model: Palm NRG body device) is a portable, non-invasive, at home skin care device. It works for with radio frequency (RF) to help users to enjoy the care skin.

Palm NRG cellulite body device (model: Palm NRG body device) is intended for delivering non thermal RF combined with massage for temporary reduction in the appearance of cellulite.

The device is a noninvasive, non-ablative device and it is supplied as non-sterile, it has 2 buttons, one for power on/off, the other one for level adjust. The main unit is equipped with accessories of an adapter and a charging base. The charging base is used to connect the adapter and the main unit.

6. Intended Use / Indications for Use

Palm NRG cellulite body device (model: Palm NRG body device) is intended for delivering non thermal RF combined with massage for temporary reduction in the appearance of cellulite.

7. Test Summary

7.1 Non-Clinical Tests Performed

Non-Clinical tests were performed on the subject device in order to validate the design and to assure conformance with the following voluntary design standards in connection with medical device electrical safety, and electromagnetic compatibility:

Palm NRG cellulite body device (model: Palm NRG body device) has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to IEC 60601-1, IEC 60601-1-11 and IEC 60601-2-57 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 standard
- Biocompatibility test according to ISO 10993-5 and ISO 10993-10 standards
- Usability test according to guidance “Applying Human Factors and Usability Engineering to Medical Devices”.
- Software verification and validation test according to the requirements of the FDA “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”

7.2 Discussion of Clinical Tests Performed

There no Clinical Tests.

8. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Palm NRG cellulite body device (model: Palm NRG body device) 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 1	Predicate Device 2	Verdict
Company	Heat In A Click LLC	Heat In A Click LLC	El Global Trade Ltd.	--
Classification Name	Electrosurgical Cutting and Coagulation Device and Accessories	Electrosurgical Cutting and Coagulation Device and Accessories	Electrosurgical Cutting and Coagulation Device and Accessories	Same
510(k) Number	Applying	K191940	K170637	--
Product Code	PBX, GEI	PBX, GEI	PBX, GEI	Same
Intended Use / Indications for Use	Palm NRG cellulite body device (model: Palm NRG body device) is intended for delivering non thermal RF combined with massage for temporary reduction in the appearance of cellulite.	Palm NRG cellulite body device (model: Palm NRG body device) is intended for delivering non thermal RF combined with massage for temporary reduction in the appearance of cellulite.	The sensiFirm device is intended for delivering non thermal RF combined with massage for temporary reduction in the appearance of cellulite.	Same
Regulation Number	878.4400	878.4400	878.4400	Same
Regulatory Class	Class II	Class II	Class II	Same
Treatment areas	Areas of the body other than the face and injured areas	Areas of the body other than the face and injured areas	Cellulite areas (buttocks, thigh, upper legs)	Same
Intended population	Adult people who desire to improve their body appearance	Adult people who desire to improve their body appearance	Adult people who desire to improve their body appearance	Same
Use environment	Home Use, self-operation by an untrained user.	Prescription use	Home Use, self-operation by an untrained user.	Same

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Verdict
Power Source(s)	Adapter:100-240Vac, 50/60Hz	Adapter:100-240Vac, 50/60Hz	100-240 Vac, 50-60 Hz	Same
Software/Firmware/Microprocessor Control	Yes	Yes	Yes	Same
Automatic Shut Off	Yes	Yes	Yes	Same
On/Off Status	Yes	Yes	Yes	Same
Low Battery	Yes	Yes	Yes	Same
Weight	0.6kg	0.6kg	192 gr/ 0.42 lb	Same
Dimensions of device(inch)	Device size:223 x 155.5 x 59mm Base size:160.6 x 52.3 x 27.1mm	Device size:223 x 155.5 x 59mm Base size:160.6 x 52.3 x 27.1mm	Hand piece:146 X 74 X 63 mm3/ 5.7*2.9*2.5 inch	Same
Device main components	Power adaptor, hand-held handpiece	Power adaptor, hand-held handpiece	Power adaptor, hand-held handpiece	Same
Mode of operation	Mechanical (vibration) massage combined with RF energy emitted from Bi-polar electrodes via a delivery Handpiece	Mechanical (vibration) massage combined with RF energy emitted from Bi-polar electrodes via a delivery Handpiece	Mechanical (vibration) massage combined with RF energy emitted from Bi-polar electrodes via a delivery Handpiece	Same
Number of electrodes	1	1	4 electrodes (2 pairs)	Same
Massage	Vibrational massage (1000 rpm, 1.5 [g]) assisted by manual manipulation	Vibrational massage (1000 rpm, 1.5 [g]) assisted by manual manipulation	Vibrational massage (1000 rpm, 1.5 [g]) assisted by manual manipulation	Same
Energy Source	RF (Bi-polar), 1 MHz	RF (Bi-polar), 1 MHz	RF (Bi-polar), 1 MHz	Same
Electrodes treatment area [mm2]	26cm²±5%	26cm²±5%	~2000 (calculated according to: 2×33×30), where – • 2 – numbers of	Same

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Verdict
			electrodes pairs • 33 - average distance between electrodes is 33 mm • electrodes length 30 mm	
Treatment regimen	Perform the treatment for 5~7 minutes on each area. 1 time per week, for 8 weeks.	Perform the treatment for 5~7 minutes on each area. 1 time per week, for 8 weeks.	20 minutes per each area, 1 time per week, for 8 weeks	Same
Energy levels (maximal and user selectable)	Up to 10±1 Watt 6 to 10±1 Watt (energy levels 1-5).	Up to 10±1 Watt 6 to 10±1 Watt (energy levels 1-5).	Up to 10 Watts. 3 energy levels(software and hardware limited):6, 8 or 10 Watts, depending on the user selection.	Same
Safety mechanism	Integrated IR thermometer, with maximal temperature (skin surface 41 ℃/ 105.8℉)	Integrated IR thermometer, with maximal temperature (skin surface 41 ℃/ 105.8℉)	Integrated IR thermometer, with maximal temperature (skin surface 41℃/ 105.8℉)	Same
Compliance with Voluntary Standards	AAMI/ES60601-1:2005/(R)2012 And A1:2012: IEC60601-1-2 IEC60601-1-6 IEC60601-1-11 IEC 60601-2-57	AAMI/ES60601-1:2005/(R)2012 And A1:2012: IEC60601-1-2 IEC60601-1-6 IEC60601-1-11 IEC 60601-2-57	IEC60601-1:2012/EN60601-1:2013 IEC 60601-1-2: 2014 IEC 60601-1-11:2015	Same
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Same

Comparison in Detail(s):

The subject device has all characteristic of predicate device K191940, a usability study is conducted. So, there is no difference between the two predicate devices.

9. Conclusion：

The subject device has all characteristic of predicate devices, and the result of usability study demonstrates that the subject device can meet the requirement for Over-The-Counter Use. Thus, the subject device is substantially equivalent to the predicate devices.