November 5, 2021

Shenzhen DJ Medical Equipment Co., Ltd.
℅ Jet Li
Regulation Manager
Guangzhou KEDA Biology Technology Co., Ltd.
6F, No.1 TianTai road, Science City, LuoGang District
Guangzhou, Guangdong
China

Re: K211055
Trade/Device Name: Microcurrent device (Model: HBR2-1)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: October 1, 2021
Received: October 7, 2021

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,

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K211055

Device Name
Microcurrent device (Model:HBR2-1)

Indications for Use *(Describe)*
The device uses microcurrent electrical to stimulate facial tissues for aesthetic purposes.

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

510k number: K211055

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

- Manufacturer Name: Shenzhen DJ Medical Equipment Co., Ltd.
- Address: Room 801, Building A, FirstFlag Science & Technology Park, No. 26 Baili Road, Nanwan Street., Longgang District, Shenzhen, Guangdong, China
- Tel.: +86-755-8557 3525
- Fax: +86-0871-67263826
- Contact Person: Feiyang Huang
- E-mail: info@djmiot.com

Application Correspondent

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

2. Subject Device Information

Type of 510(k) submission: Traditional

Common Name: Stimulator, Nerve, Transcutaneous, Over-The-Counter

Trade Name: Microcurrent device (Model: HBR2-1)

Classification Name: Stimulator, Nerve, Transcutaneous

Review Panel: Neurology, Physical Medicine

Product Code: NFO

Regulation Number: 882.5890

Regulation Class: 2

3. Predicate Device Information

Sponsor	TAMA Research Corporation	Li-Tek Electronics Technologies
Device Name	TAMA BEMS Device	Micro-current Wrinkle Removing Facial Service, model EP-400
510(k) Number	K173093	K162106
Product Code	NFO	NFO
Regulation Number	882.5890	882.5890
Regulation Class	2	2

4. Device Description

The Microcurrent device (Model: HBR2-1) is a hand-held, non-sterile, reusable device designed to achieve the cosmetic effect. The device consist of main unit and wireless charging station with undetachable USB cable. The device is supplied by internal rechargeable lithium battery. It can be recharged by external charger through the charging station.

The device design with Micro current output stimulation function. The MCU-controlled microcurrent circuit generates a low-frequency microcurrent which will applied in the facial skin to do facial stimulation. In the microcurrent stimulation mode, there is ten levels of output intensity which would be adjusted by the button in the device.

The device is only intended for home use.

5. Intended Use / Indications for Use

The device uses microcurrent electrical to stimulate facial tissues for aesthetic purposes.

6. Performance Summary

The device conforms to the following standards:

- IEC 60601-1: 2012 Medical electrical equipment Part 1: General requirements for basic safety and essential performance

- IEC 60601-1-2:2014, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests.
- IEC 60601-1-11:2015 Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment
- IEC 60601-2-10: 2016, Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Test for in vitro cytotoxicity.
- ISO 10993-10:2010 Biological evaluation of medical devices Part 10: Test for irritation and skin sensitization.

Software Verification and Validation Testing

Software verification and validation testing were conducted and its 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 determined to beof "moderate" level of concern.

Usability Testing

Usability testing was conducted to demonstrate that the device and its labeling can meet the following requirements:

1) the lay user can self-select themselves as being appropriate users of this device by the external box labeling,

2) the lay user can apply the treatment safely and correctly according to the instructions for use, and

3) the lay user can understand all indications, contraindications, warnings and precautions, and be able to identify whether they are within any contraindicated group; and be able to understand the user manual.

Clinical Testing

Clinical data were not required in this submission to support a finding of substantial equivalence.

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of the Microcurrent device (Model: HBR2-1) 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** (K211055)	**Primary Predicate Device** (K173093)	**Reference device** (K162106)
Device Name and Model	Microcurrent device Model: HBR2-1	TAMA BEMS Device	Micro-current Wrinkle Removing Facial Service, model EP-400
Intended Use & Indications for Use	The device uses microcurrent electrical to stimulate facial tissues for aesthetic purposes.	The TAMA BEMS Device uses microcurrent electrical to stimulate facial tissues for aesthetic purposes.	The device is intended for facial stimulation by electrode heads for cosmetic use. The device is also intended for the treatment of periorbital wrinkles with red Light Emitting Diode (LED) head. It is for over-the-counter use.
Prescription Status	Over-the-Counter Use (OTC) Note: Usability study provided to demonstrate OTC use	Prescription Use (Rx) Only	Over-the-Counter Use (OTC)
Number of outputs mode	1	4	1
Number of channels	1	1	1
Output Intensity Level	10	--	--
Stimulated muscles	Face	Face	For micro current stimulation: Face; For Red light: periorbital
Maximum output voltage	0.54V@500Ω 2.24V @ 2kΩ 10.8V @ 10kΩ	±0.400 @500Ω ±1.600 @2 k Ω ±8.00 @10k Ω	1.23V @ 500Ω 3.64V @ 2kΩ 10.9V @ 10kΩ
Maximum Output Current	1.08mA @ 500Ω 1.12mA@2kΩ 1.08mA@10kΩ	±0.800 @500 Ω ±0.800 @2 k Ω ±0.800 @10k Ω	2.46mA @ 500Ω 1.82mA @ 2kΩ 1.09mA @ 10kΩ
Frequency range (Hz)	8.34Hz	Frequency (Hz) [or Rate (pps)] 0.045 – 2560	59.3Hz

Pulse width	60ms	Pulse Duration (msec) 52.6 – 2400	4ms
Contraction and Relaxation time	Adjustable, due to different modes.	Adjustable, due to different modes.	Adjustable, due to different modes.
Net Charge, (μC) @ 500 Ω	0μC @500Ω	0μC @500Ω	9.04μC@ 500Ω
Maximum Current Density (mA/cm² @ 500Ω)	0.0325 mA/cm² @500Ω	1.591mA/cm2@500Ω	Bigger electrode head: 0.044 mA/cm²@ 500Ω Smaller electrode head: 0.42 mA/cm²@ 500Ω
Maximum pow er Density	106uW/cm² @500Ω	318uW/cm2 @500Ω	Bigger electrode head 0.014 mW/ cm²@ 500Ω Smaller electrode head 0.139 mW/ cm²@ 500Ω
Timer Range	10 minutes	0-30 minutes	10 minutes
Additional Features			
Power	Adaptor Output: DC 5V, 0.3A	Internal 4.3V rechargeable Lithium Polymer battery	1200mAh lithium battery
indication display	pow er on, pow er off, operation mode.	On/Off Display Status, Low Battery, Voltage/Current Level	On/Off Status, Low Battery, Voltage/Current Level
Dimension	About 180 mm*40mm	3x5x0.7(in.)	--;
Weight	80g	9.5 ounces	--;
Housing Materials	ABS	Anodized aluminum 6061	ABS plastic

Microprocessor control	Yes	Yes	Yes
Automatic Overload trip	Yes	Yes	Yes
Automatic no-load trip	Yes	Yes	Yes
Automatic shut-off	Yes	Yes	Yes
User override control	Yes	Yes	Yes
Environment for operating	Temperature: +18° C ~ +40° C Relative humidity: 35 % ～ 75 %	--;	Temperature: 5 ~ 40° C
Environment for storage	Temperature: -10° C ~ +55° C Relative humidity: 20 % ～ 80 %	--;	Temperature: -25 ~70° C Humidity: 10 ~90% RH
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5, ISO10993-10 and IEC 62471:2006 requirements.
Electrical Safety	Comply with IEC 60601-1 and IEC 60601-2-10; IEC60601-2-57 IEC60601-1-11	Comply with IEC 60601-1 and IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2

Final Conclusion:

The subject device “Microcurrent device (Model: HBR2-1)” is Substantial Equivalence to the predicate device.