DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 27, 2016

M.i.tech Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
Lk Consulting Group USA, Inc.
800 Roosevelt Ste 417
Irvine, California 92620

Re: K160893
Trade/Device Name: Hanarocare Reju
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: June 10, 2016
Received: June 17, 2016

Dear Ms. Chung:

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 yours,

William J. Heetderks -A

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -A
Date: 2016.07.27 11:43:29 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K160893

Device Name

HANAROCare ReJu

Indications for Use *(Describe)*

HANAROCare ReJu is indicated for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.

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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510(k) Summary

(K160893)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

1. **Date:** 07/18/2016

2. **Applicant / Submitter**

M.I.TECH Co., Ltd.
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3. **U.S. Designated Agent**

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4. **Trade/Proprietary Name:**

HANAROCare ReJu

5. **Common Name:**

Transcutaneous Electrical Nerve Stimulator

6. **Classification:**

Stimulator, Nerve, Transcutaneous, Over-the-counter (21 CFR 882.5890, Product code NUH, Neurology)

7. **Device Description:**

HANAROCare ReJu is a personal stimulator that reduces the pain by delivering a specific rhythmic electric stimulation to the nerves and the muscles through electrode attached to the skin (Transcutaneous Electrical Nerve Stimulation). Electric current delivered to the nerves reduces the pain. The subject device offers four different stimulation modes (Mode 1, Mode 2, Mode 3, and Combination Mode). It is composed of as stimulator, silicon electrode, and gel pads.

8. Indication for use:

HANAROCare ReJu is indicated for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.

9. Predicate Device:

- Primary Predicate Device: Prospera OTC TENS Electronic Pulse Massager(model: PL029) by Prospera Corporation (K122744)
- Reference Predicate Device:
  - HIVOX Electric Stimulator OTC TENS, Rapid Relief by HIVOX BIOTEK INC (K140650)
  - EasyStim TN28_OTC by EasyMed Instruments Co., Ltd. (K140168)
  - Electronic Pulse Stimulator/PL-029K by Shenzhen Jingkehui Electronic Co., Ltd. (K141260)

10. Substantial Equivalence:

	Subject Device	Primary Predicate Device	Reference Predicate Device	Reference Predicate Device	Reference Predicate Device
510k #	-	K122744	K140650	K140168	K141260
Manufacturer	M.I.Tech Co., Ltd.	Prospera Corporation	HIVOX BIOTEK INC	EasyMed Instruments Co., Ltd.	Shenzhen Jingkehui Electronic Co., Ltd.
Trade/Proprietary Name	HANAROCareReJu	Prospera OTC TENS Electronic Pulse Massager(model: PL029)	HIVOX Electric Stimulator OTC TENS, Rapid Relief	EasyStim TN28_OTC	Electronic Pulse Stimulator/PL-029K
Product Code	NUH	NUH, NGX	NUH	NUH	NUH
Type of Use	Over the Counter	Over the Counter	Over the Counter	Over the Counter	Over the Counter
Intended Use	HANAROCareReJu is indicated for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.	To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.	The HIVOX Electric Stimulator OTC TENS, Rapid Relief Pennypad PP-904. is indicated for temporary relief of pain associated with sore and aching muscles in the upper and lowerextremities (arm and/or leg), and lower back due to strain fromexercise or normal household and work activities.	It is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, or legs due to strain from exercise or normal household and work activities.	To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist,back, arm, and leg, due to strain from exercise or normal household and work activities
Principle of Operation	to generate small pulses of electrical current and deliver the pulses to a user's skin through electrode adhesive pads	to generate small pulses of electrical current and deliver the pulses to a user's skin through electrode adhesive pads	to generate small pulses of electrical current and deliver the pulses to a user's skin through electrode adhesive pads	to generate small pulses of electrical current and deliver the pulses to a user's skin through electrode adhesive pads	to generate small pulses of electrical current and deliver the pulses to a user's skin through electrode adhesive pads
Power Source	Lithium-polymer, 3.7V	3V Battery	CR2032 Lithium 3V	2 Alkaline AA 1.5V (LR6) Batteries	2pcs AAA batteries,3V
Number of Output Modes	4	8	3	8	8
Number of output channels	1	2(Synchronous/Alternating)	1	2	2
Pulse strength	0~15 Stages	0~10 Stages	0~15 Stages	Not specified	Not specified

Treatment Timer		20 minutes fixed	5min, 10min	20 minutes fixed	20min, 25min, 30min,40min depending on preset program	Not specified
Output Waveform		Monophasic	Monophasic	Symmetrical Biphasic	Monophasic rectangular	Not specified
Shape		Rectangular	Rectangular	Rectangular	Biphasic rectangular	Not specified
Housing Materials and Construction		Retardant Polycarbonate	ABS	Silicone	ABS	Not specified
Weight(grams)		11	181.4	Not specified	146.5	Not specified
Dimensions(mm) [W x H xD]		36 x 35 x 13.7	59 x 200 x 21	113 x 70x 10	66×136×30.7	Not specified
Maximum Output Voltage (volts)	@500Ω	(±10%) • Mode 1 : 64 • Mode 2 : 67 • Mode 3 : 59 • Combination : This mode cycles the above modes	49.6	57.6	68	(±20%) • Mode 1: 46.0 • Mode 2: 59.6 • Mode 3: 49.2 • Mode 4: 64.8 • Mode 5: 37.2 • Mode 6: This mode cycles the above modes. • Mode 7: 71.2 • Mode 8: 64.0
	@2kΩ	(±10%) • Mode 1 : 113 • Mode 2 : 119 • Mode 3 : 108 • Combination: This mode cycles the above modes.	99.2	89.6	102	(±20%) • Mode 1: 86.4 • Mode 2: 111 • Mode 3: 80 • Mode 4: 90.4 • Mode 5: 64.8 • Mode 6: This mode cycles the above modes. • Mode 7: 122 • Mode 8: 89.6

	@10kΩ	(±10%) <15	114	96.0	110	(±20%) • Mode 1: 116 • Mode 2: 146 • Mode 3: 138 • Mode 4: 106 • Mode 5: 111 • Mode 6: This mode cycles the above modes. • Mode 7: 136 • Mode 8: 96.8
Maximum Output Current (mA)	@500Ω	(±10%) • Mode 1 : 128 • Mode 2 : 134 • Mode 3 : 118 • Combination: This mode cycles the above modes.	18	115.2	113	(±20%) • Mode 1: 92.0 • Mode 2: 119.2 • Mode 3: 98.4 • Mode 4: 129.6 • Mode 5: 74.4 • Mode 6: This mode cycles the above modes. • Mode 7: 142.4 • Mode 8: 128.0
	@2kΩ	(±10%) • Mode 1 : 57 • Mode 2 : 60 • Mode 3 : 54 • Combination: This mode cycles the above modes.	3.2	44.8	51	(±20%) • Mode 1: 43.2 • Mode 2: 55.5 • Mode 3: 40 • Mode 4: 45.2 • Mode 5: 32.4 • Mode 6: This mode cycles the above modes. • Mode 7: 61 • Mode 8: 44.8

	@10kΩ	(±10%) <15	0.6	9.6	11	(±20%) • Mode 1: 11.6 • Mode 2: 14.6 • Mode 3: 13.8 • Mode 4: 10.6 • Mode 5: 11.1 • Mode 6: This mode cycles the above modes. • Mode 7: 13.6 • Mode 8: 9.7
Max Pulse Freq.(Hz)		(±10%) • Mode 1 : 2Hz • Mode 2 : 16.7Hz • Mode 3 : 33.3Hz • Combination: This mode cycles the above modes.	0.5~86	2, 5, and 40 (Fixed)	1~150	(±20%) • Mode 1: 54.3 • Mode 2: 35.7 • Mode 3: 62.5 • Mode 4: 6.7 • Mode 5: 83.3 • Mode 6: This mode cycles the above modes. • Mode 7: 19.8 • Mode 8: 1.2
Pulse period, msec		(±10%) • Mode 1 : 500 • Mode 2 : 60 • Mode 3 : 30 • Combination: This mode cycles the above modes.	Not specified	Not specified	Not specified	12~832
Pulse Width(μsec)		(±10%) • Mode 1 : 115 • Mode 2 : 75 • Mode 3 : 65 • Combination: This mode cycles the above modes.	100~200	200(fixed)	50-250, in steps of 50	50~100

Maximum Phase Charge(μC)	@500Ω	((±10%) • Mode 1 : 14.72 • Mode 2 : 10.05 • Mode 3 : 7.67 • Combination: This mode cycles the above modes.	23	23.04	20.02	(±20%) • Mode 1: 19.9 • Mode 2: 6.0 • Mode 3: 4.9 • Mode 4: 6.5 • Mode 5: 3.7 • Mode 6: This mode cycles the above modes. • Mode 7: 33.0 • Mode 8: 25.6
Maximum Current Density (mA/cm2, r.m.s.)	@500Ω	(±10%) <Standard Electrode: 12.57cm2> • Mode 1 : 0.154 • Mode 2 : 0.377 • Mode 3 : 0.437 • Combination: This mode cycles the above modes. <Monarch Electrode: 38.09 cm2> • Mode 1 : 0.051 • Mode 2 : 0.124 • Mode 3 : 0.144 • Combination: This mode cycles the above modes.	1.4	2.828	0.188	(±20%) • Mode 1: 5.75 • Mode 2: 7.45 • Mode 3: 6.15 • Mode 4: 8.10 • Mode 5: 4.65 • Mode 6: This mode cycles the above modes. • Mode 7: 8.90 • Mode 8: 8.00

Maximum Average Power Density (mW/cm2)	@500Ω	(±10%) <Standard Electrode: 12.57cm2> • Mode 1 : 0.15 • Mode 2 : 0.893 • Mode 3 :1.2 • Combination: This mode cycles the above modes. <Monarch Electrode: 38.09 cm2> • Mode 1 : 0.049 • Mode 2 : 0.295 • Mode 3 : 0.396 • Combination: This mode cycles the above modes.	230	163	7.52	(±20%) • Mode 1: 3.10 • Mode 2: 0.79 • Mode 3: 0.95 • Mode 4: 0.18 • Mode 5: 0.72 • Mode 6: This mode cycles the above modes. • Mode 7: 2.91 • Mode 8: 0.12

The operational principle of the above listed predicate devices is to generate small pulses of electrical current and deliver the pulses to a user's skin through electrode adhesive pads such that the underlying nerves are activated and the pain associated with sore and aching muscles is temporarily relieved. Similarly, the operational principle of the subject device manufactured is to generate small pulses of electrical current and deliver the pulses to an ordinary user's skin through electrode adhesive pads such that the underlying nerves are activated and the pain associated with sore and aching muscles is temporarily relieved.

The table above illustrates the subject device's comparison with the predicate devices. It indicates that the technical characteristics, features, specifications and intended use of the subject device are substantially equivalent to those of the predicate devices. The stimulation parameters of subject device are all in the range of those of predicate devices. The design differences between the subject device and the predicate devices are insignificant and does neither affect the intended use, nor alter the operational principle of the subject device.

The major difference between the subject device and the predicate devices is that the subject device has the safety feature of reducing and cutting off the output when it detects more than 3kΩ. If the voltage detected is more than 3kΩ resistive load, the device will determine that the electrode is not properly attached to the skin and will reduce the maximum output voltage to less than 15 V at open load. It will also alarm the user with LED light and the buzzer sound. If the condition lasts more than 3 minutes, it will automatically cut off the output and turn the device off. This feature is for safety and does not affect the performance of the

device; therefore, based on the information provided in this submission, we conclude that the subject device is substantially equivalent to the predicate devices.

11. Performance Data:

- Shelf Life Test: The following shelf life has been performed to validate 2 year shelf life of the subject device.
  - Visual Inspection
  - Gel Pad Adhesive Strength Test
  - Electrical Conductivity Test
- Biocompatibility Test: The following biocompatibility tests for gel pad have been performed to validate the biocompatibility of the patient contacting part.
  - ISO 10993-5: Cytotoxicity Test (Aggar Diffusion Assay)
  - ISO 10993-10: Primary skin irritation study in rabbits (4 hour semi-occlusive application)
  - ISO 10993-10: Contact Hypersensitivity in Albino Guiana Pigs Maximization Test
- The electrical tests for the subject device were evaluated in accordance with the following method and standards.

No.	Items	Test Method / Standard
1	IEC 60601-1 General requirements for basic safety and essential performance	IEC 60601-1:2005(Third Edition)
2	IEC 60601-2-10 Particular requirements for the basic safety and essential performance of nerve and muscle stimulators	IEC 60601-2-10:2012(Second Edition) for use in conjunction with IEC 60601-1:2005(Third Edition)
3	IEC 60601-1-11 Medical Electrical Equipment: 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 60601-1-11(First Edition): 2010
4	IEC 60601-1-6 General requirements for safety-Collateral Standard: Usability	IEC 60601-1-6:2010(Third Edition)
5	EMC Test	IEC 60601-1-2:2007
6	IEC 62366 Medical devices-Application of usability engineering to medical devices	IEC 62366:2007(First Edition) for use in conjunction with IEC 60601-1-1-6:2010

7	IEC 62304Medical device software-Software life-cycle processes	IEC 62304:2006(First Edition)
8	Atmospheric Preconditioning(Ambient) Atmospheric Conditioning(Hot, Humid) Compression(Machine Apply and Release) Vibration(Fixed Displacement) Shock(Drop) Vibration(Random)	ISTA 2014 Integrity Test Procedure 2A
9	RoHS verification	IEC 62321:2008: Procedures for the Determination of Levels ofSix Regulated Substances in Electrotechnical Products

- Performance Test:
  Performance test was conducted to evaluate the characteristic parameters of the stimulus output waveform, and verify that the measurement values meet the criteria.

- Usability Study:
  Thirty (30) different users of various age, gender, and educational background participated in the study. This study was to evaluate their performance in using various functions of the HANAROCare ReJu. The test result demonstrated the ease to use the HANAROCare ReJu.

12. Conclusion:

The subject device and the predicate device are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. The new device does not introduce a fundamentally new scientific technology. Therefore, it is our opinion that the HANAROCare ReJu described in this submission is substantially equivalent to the predicate device.