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

August 6, 2014

IQ Technologies, Inc.
Elli Josef
1631 E. Sunset Rd., Ste. C 103
Las Vegas, NV 89119

Re: K131290
Trade/Device Name: IQ Technologies
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electric nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH; NGX
Dated: June 30, 2014
Received: July 2, 2014

Dear Mr. Josef:

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" (21CFR 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,

Felipe Aguel -S

for Carlos L. Peña, Ph.D., M.S.
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)*
K131290

Device Name
IQ Technologies

Indications for Use *(Describe)*
To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.08.06 22:22:02 -04'00'

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 safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter's Information

Submitter: IQ Technologies Inc.
Address: 1631 E. Sunset Road, C103, Las Vegas, NV 89119
Contact Person: Elli Josef
Tel: 702-260-8829
Fax: 702-260-8840
Email: elijosef57@gmail.com
Date of Preparation: 04/11/2013

2. Correspondent's Information

Correspondent: IQ Technologies Inc.
Address: 1631 E. Sunset Road, C103, Las Vegas, NV 89119
Contact Person: Elli Josef
Tel: 702-260-8829
Fax: 702-260-8840
Email: elijosef57@gmail.com

3. Subject Device

Trade/Device Name: IQ Technologies
Common Name: Transcutaneous electrical nerve stimulator (TENS) and Powered Muscle Stimulator (PMS)
Classification Name: Stimulator, Nerve, Transcutaneous, Over-The-Counter (OTC)
Regulation Description: Transcutaneous electrical nerve stimulator for pain relief
Regulation Medical Specialty: Neurology
Review Panel: Neurology
Product Code: NUH, NGX
Regulation Number: 21 CFR 882.5890
Device Class: II
Use: Over-The-Counter

4. Predicate device

Predicate Device: Powered Muscle Stimulator, JQ-5C
510(k) Number: K102598
Use: Over-The-Counter
Submitter: Hi-Dow International, Inc.

Predicate Device: TENS&PMS
510(k) Number: K121757
Use: Over-The-Counter
Submitter: Healthmate International, LLC

5. Description of Subject Device

The subject device is a Transcutaneous Electrical Nerve Stimulator (TENS) and Powered Muscle

Stimulator (PMS), intended for the over-the-counter use to temporarily relieve pain and stimulate muscle in different body areas. The double-channel subject device, which is compact, portable, and microprocessor-controlled, delivers a gentle electrical pulse through the connecting wires and electrode pads to the user's skin for pain relief and muscle stimulation. The electrode pad used consists of gel, carbon film, cloth backing, and electrode connector, which is 510(k)-cleared and biocompatible. According to the need of users, the pulse intensity can be adjustable on the front control panel of the device.

6. Intended Use of Subject Device

TENS:

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

PMS:

It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

7. Summary of Substantial Equivalence

The following table summarizes the comparison between the subject device and predicate devices, indicating the technical characteristics, specifications, and intended use of the subject device are substantially equivalent to those of the predicate devices.

	Subject Device	Predicate Device	Predicate Device
510(k) Number	K131290	K102598	K121757
Device Name	IQ Technologies	Hi-Dow	HealthmateForever
Intended Use	To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	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. It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	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. It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.
Power Source	DC 3.7V Lithium Battery	DC 3.7V Lithium Battery	DC 3.7V Lithium Battery
Number of Output Channels	2	2	2

Automatic Overload Trip	No	No	No
Automatic No-Load Trip	No	No	No
Automatic Shut Off	Yes	Yes	Yes
User Override Control	Yes	Yes	Yes
Indicator	Yes	Yes	Yes
Waveform	Pulsed	Pulsed	Pulsed
Shape	Rectangular	Rectangular	Rectangular
Maximum output voltage (Volts +/- 20%) at 500Ω	Mode 1: 42 Mode 2: 63.2 Mode 3: 64 Mode 4: 34.4 Mode 5: 32 Mode 6: This mode cycles the above five modes	62.4	70
Maximum output voltage (Volts +/- 20%) at 2KΩ	Mode 1: 80.8 Mode 2: 94.4 Mode 3: 87.2 Mode 4: 68 Mode 5: 64 Mode 6: This mode cycles the above five modes	79.2	90
Maximum output voltage (Volts +/- 20%) at 10kΩ	Mode 1: 129 Mode 2: 129 Mode 3: 96.8 Mode 4: 128 Mode 5: 119 Mode 6: This mode cycles the above five modes	84	100
Maximum output current (mA +/- 20%) at 500Ω	Mode 1: 84 Mode 2: 126.4 Mode 3: 128 Mode 4: 68.8 Mode 5: 64 Mode 6: This mode cycles the above five modes	124.8	140
Maximum output current (mA +/- 20%) at 2KΩ	Mode 1: 40.4 Mode 2: 47.2 Mode 3: 43.6 Mode 4: 34 Mode 5: 32 Mode 6: This mode cycles the above five modes	39.6	45

Maximum output current (mA +/- 20%) at 10KΩ	Mode 1: 12.9 Mode 2: 12.9 Mode 3: 9.7 Mode 4: 12.8 Mode 5: 11.9 Mode 6: This mode cycles the above five modes	8.4	10
Pulse Width (μSec)	100	100	90
Pulse period (mSec)	10~840	16.3~781	10~836
Frequency (Hz)	Mode 1: 69.4 Mode 2: 12.3~54.3 Mode 3: 1.2 Mode 4: 100 Mode 5: 100 Mode 6: This mode cycles the above five modes	61.3	100
Maximum Phase charge (μC) at 500Ω	16.8	17.9	15.7
Maximum current density (mA/cm^2) at 500Ω	Mode 1: 3.36 Mode 2: 5.06 Mode 3: 5.12 Mode 4: 2.75 Mode 5: 2.56 Mode 6: This mode cycles the above five modes	9.92	Mode 1: 6.48 Mode 2: 5.6 Mode 3: 7.2 Mode 4: 5.6 Mode 5: 5.6 Mode 6: This mode cycles the above modes
Maximum average power density (mW/cm^2) at 500Ω	Mode 1: 2.11 Mode 2: 0.85~3.75 Mode 3: 0.08 Mode 4: 2.05 Mode 5: 1.64 Mode 6: This mode cycles the above five modes	2.72	Mode 1: 0.52 Mode 2: 0.39 Mode 3: 0.65 Mode 4: 0.39 Mode 5: 0.39 Mode 6: This mode cycles the above modes
Compliance with Voluntary Standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10
Compliance with 21 CFR 898	Yes	Yes	Yes

8. Substantial Equivalence

The operational principle of the above predicate devices is to generate small pulses of electrical current and delivers the pulses to the user's skin through adhesive electrode pads such that the underlying nerves and/or muscles are activated.

Identically, the subject device generates small pulses of electrical current and delivers the pulses to the user's skin through adhesive electrode pads such that the underlying nerves and/or muscles are activated.

The comparison between the subject device and predicate devices demonstrates the technical characteristics, specifications, and intended use of the subject device are substantially equivalent to those of the predicate devices.

The differences, such the output voltage and current, between the subject device and the predicate devices are insignificant in terms of safety or effectiveness. The verification and validation tests, such as IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-10, further demonstrate these differences maintain the same safety and effectiveness as those of the 510(k) cleared predicate devices. In other words, these differences do not affect the intended use or alter the fundamental technology of the device. There are no new safety or effectiveness issues concerning the subject device, which offers substantially equivalent technical specifications, features, intended use, and effective results as the predicate devices.

Concerns of the safe and proper use of the electrode pads have been fully addressed by making the use conscious of the proper placement of the electrode pads and appropriate operations of the device through details in the labeling. The electrode pads cleared in K090198 are to be used with the subject device.

9. Non-Clinical Tests Performed

The subject device does not conduct, nor rely upon, clinical tests to determine substantial equivalence. 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.

(a) IEC 60601-1 "Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance".
(b) IEC 60601-1-2 "Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests".
(c) IEC 60601-2-10 "Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators".

In addition to the compliance of voluntary standards, the verification of software used in the subject device has been carried out according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. The biocompatible electrodes, as the accessory of the subject device, also meet the requirement of safety.

10. Conclusion

The tests performed and the comparison of technical characteristics, specifications, and intended use demonstrate the subject device is substantially equivalent to the predicate device. Therefore, the subject device is as safe and effective as the foregoing identified OTC predicate devices that have been legally marketed in the United States.