**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

May 26, 2017

IQ Technologies Inc.
% Bill Dai
Dr Certification LLC
1142 S. Diamond Bar Blvd, #861
Diamond Bar, California 91765

Re: K170659
Trade/Device Name: IQ Technologies
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH;NGX
Dated: January 15, 2017
Received: March 3, 2017

Dear Bill Dai:

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,

William J. Heetderks -S
2017.05.26 11:53:27 -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)*
N/A

Device Name
IQ Technologies Pro IVs, Pro V, and Pro VI

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)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**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: 6672 Spencer St., Ste 800, Las Vegas, NV 89119
Contact Person: Elli Josef
Tel: 702-260-8829
Fax: 702-260-8840
Email: elijosef57@gmail.com
Date of Preparation: 11/01/2016

**2. Correspondent's Information**

Dr Certification LLC
1142 S. Diamond Bar Blvd, #861
Diamond bar, CA 91765

**3. Subject Device**

Trade/Device Name: IQ Technologies Pro IVs, Pro V, and Pro VI
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: IQ Technologies
510(k) Number: K131290
Use: Over-The-Counter
Submitter: IQ Technologies Inc.

**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.

| | Predicate Device | Subject Device |
|---|---|---|
| 510(k) Number | K131290 | N/A |
| Submitter | IQ Technologies Inc. | IQ Technologies Inc. |
| Device Name | IQ Technologies | IQ Technologies Pro IVs, Pro V, and Pro VI |
| 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.<br><br>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, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.<br><br>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 |
| Number of Output Channels | 2 | 2 |
| Automatic Overload Trip | No | No |
| Automatic No-Load Trip | No | No |
| Automatic Shut Off | Yes | Yes |
| User Override Control | Yes | Yes |
| Indicator | Yes | Yes |
| Waveform | Pulsed | Pulsed |
| Shape | Rectangular | Rectangular |
| Maximum output voltage (Volts +/- 20%) at 500Ω | 64 | 66 |
| Maximum output voltage (Volts +/- 20%) at 2KΩ | 94.4 | 100 |
| Maximum output voltage (Volts +/- 20%) at 10kΩ | 129 | 128 |

| | | |
|---|---|---|
| Maximum output current (mA +/- 20%) at 500Ω | 128 | 132 |
| Maximum output current (mA +/- 20%) at 2KΩ | 47.2 | 50 |
| Maximum output current (mA +/- 20%) at 10KΩ | 12.9 | 12.8 |
| Pulse Width (μSec) | 100 | 100 |
| Pulse period (mSec) | 10~840 | 10~833 |
| Frequency (Hz) | 1.2~100 | 1.2~100 |
| Maximum Phase charge (μC) at 500Ω | 16.8 | 17.3 |
| Maximum current density ($mA/cm^2$) at 500Ω | 3.36 | 3.3 |
| Maximum average power density ($mW/cm^2$) at 500Ω | 2.11 | 2.0 |
| 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 |
| Compliance with 21 CFR 898 | 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 between the subject device and the predicate devices are insignificant in terms of safety or effectiveness. The verification and validation tests 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 K131290 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.