DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 5, 2016

Neurometrix, Inc.
Rainer Maas
Director of QA/RA/Compliance
1000 Winter Street
Waltham, Massachusetts 02451

Re: K152954
Trade/Device Name: Quell
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: October 5, 2015
Received: October 7, 2015

Dear Mr. Maas:

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 -S

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)*
K152954

Device Name
Quell

Indications for Use *(Describe)*
Quell is intended for use as a transcutaneous electrical nerve stimulation device for temporary relief of pain associated with sore and aching muscles in the lower extremities due to strain from exercise or normal household and work activities.

Quell is intended for use as a transcutaneous electrical nerve stimulation device for the symptomatic relief and management of chronic intractable pain.

The device may be used during sleep. The device is labeled for use only with compatible NeuroMetrix electrodes.

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
for
Quell®

SPONSOR

NeuroMetrix, Inc.
1000 Winter Street
Waltham, MA 02451 USA

Contact Person: Rainer Maas
Telephone: (781) 314-2781
Date Prepared: October 5, 2015

DEVICE NAME

Proprietary Name: Quell
Common/Usual Name: Transcutaneous Electrical Nerve Stimulator, TENS
Classification Name: 882.5890 NUH
Transcutaneous electrical nerve stimulator for pain relief

PREDICATE DEVICE

NeuroMetrix ASCEND (K140333)

INTENDED USE

Quell is intended for use as a transcutaneous electrical nerve stimulation device for temporary relief of pain associated with sore and aching muscles in the lower extremities due to strain from exercise or normal household and work activities.

Quell is intended for use as a transcutaneous electrical nerve stimulation device for the symptomatic relief and management of chronic intractable pain.

The device may be used during sleep. The device is labeled for use only with compatible NeuroMetrix electrodes.

DEVICE DESCRIPTION

Quell is a single output-mode transcutaneous electrical nerve stimulator for symptomatic relief and management of chronic intractable pain that is sold without a prescription. The device utilizes a microprocessor running embedded software to control a high-voltage circuit that generates current-regulated stimulating pulses with specific technical characteristics including pulse shape, amplitude, duration, pattern, and frequency. The device is powered by an embedded rechargeable Lithium-Ion battery that is charged through a USB cable connected to an AC adapter.

The device delivers electrical stimulation to the user through a disposable electrode placed on the user's body. The device is labeled for use only with compatible NeuroMetrix electrodes (e.g., K140586), to which it connects through insulated female medical snap connectors embedded within its housing; no lead-wires are used.

The user interface consists of a push button and a linear 6 LED array consisting of 5 white LEDs and 1 amber LED. The push button initiates stimulation and controls the intensity. The LED array indicates stimulation status, battery charging, and error conditions.

A Quell user may initiate therapy, halt therapy, increase stimulation intensity and decrease stimulation intensity through a wireless control mechanism that is collectively referred to as the "virtual button." The virtual button is available through the Quell mobile app and is intended for use in the same environments as the Quell device.

The wireless technology details are summarized below.

Form of Wireless Technology	Bluetooth® low energy
Type	BLE113 Bluetooth® Smart Module (Silicon Labs, Austin, TX)
RF Frequencies	2.400 GHz - 2.4835 GHz ISM band
Maximum Output Power	0 dBm
Maximum Receiver Sensitivity	-93 dBm
Range	10 m (unobstructed)

COMPARISON TO PREDICATE

Quell has identical indications for use as the cleared ASCEND device (K140333); both are intended for use as a transcutaneous electric nerve stimulation device for the symptomatic relief and management of chronic intractable pain, and may be used during sleep. Both devices are only labeled for use with compatible NeuroMetrix electrodes.

The Quell and ASCEND devices have similar technological characteristics as listed below.

- One stimulation channel
- Single output mode
- User controlled intensity
- Fixed therapy session timer
- LED indicators (no intensity display)
- Powered by battery

As demonstrated by the table below, there are no significant differences in basic unit characteristics between Quell and ASCEND that would raise new questions of safety or effectiveness.

Basic Unit Characteristics

Parameter	**Quell**	**ASCEND K140333**
Device Name and Model Number	Quell	ASCEND
Manufacturer	NeuroMetrix	NeuroMetrix
Power Source(s)	Rechargeable 3.7V Lithium-Ion battery	Rechargeable 3.7V Lithium-Ion battery
Method of Line Current Isolation	Cannot charge while used	Cannot charge while used
Patient Leakage Current		
Normal Condition	<10 µA	<10 µA
Single Fault Condition	<100 µA	<100 µA
Avg. DC current through electrodes when device on but no pulse applied (µA)	< 1 µA	< 1 µA
Number of Output Modes	1	1

No. Output Channels	Synchronous or alternating	1	1
	Method of chan. isolation	N/A	N/A
Regulated Current or Voltage		Current	Current
Software/Firmware/Micro. Control		Yes	Yes
Automatic Overload Trip?		Yes	Yes
Automatic No-Load Trip? (open circuit)		Yes	Yes
Automatic Shut Off?		Timer, trip	Timer, trip
User Override Control?		4 button presses	Double tap
Indicator Display:	On/Off Status?	Yes	Yes
	Low Battery?	Yes	Yes
	Voltage/Current Level?	No	No
Timer Range		60 minutes	60 minutes
Compliance with Voluntary Standards		IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 62304 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 62304
Compliance with 21 CFR 898		Yes	Yes
Weight		62g (2.2 oz)	82g (2.9 oz)
Dimensions (W x H x D)		11mm (0.4") x 74mm (2.9") x 98 mm (3.9")	16mm (0.6") x 63mm (2.5") x176mm (6.9")
Housing Materials & Construction		Plastic, Nylon, Spandex, Velcro®	Plastic, Nylon, Velcro®

A comparison of output specifications is provided in the table below. The only difference is that Quell has maximum phase duration of 200 μs versus 100 μs for ASCEND. This leads to higher maximum phase charge, maximum current density, maximum average current, and maximum average power density. Although larger in Quell, these values are within the range of other 510(k) cleared transcutaneous electrical nerve stimulators. As a result, the increased phase duration does not raise new questions of safety or effectiveness

Output Specifications

Parameter		**Quell**	**ASCEND K140333**
Mode or Program Name		Single mode	Single Mode
Waveform		Biphasic	Biphasic
Shape (output current)		Rectangular	Rectangular
Maximum Output Voltage (10 +/- %)		50 V @500 Ω 100 V @2000 Ω 100 V @10000 Ω	50 V @500 Ω 100 V @2000 Ω 100 V @10000 Ω
Maximum Output Current (10 +/- %)		100 mA @500 Ω 50 mA @2000 Ω 10 mA @10000 Ω	100 mA @500 Ω 50 mA @2000 Ω 10 mA @10000 Ω
Duration of primary (depolarizing) phase		100 - 200 μs	100 μs
Pulse Duration (both phases)		200 - 400 μs, 30 μs inter-phase delay	200 μs, 30 μs inter-phase delay
Frequency		Random with 80 Hz mean (Range 60 – 100 Hz)	Random with 80 Hz mean (Range 60 – 100 Hz)
For multiphasic waveforms only:	Symmetrical phases	Yes	Yes
	Phase Duration	100 - 200 μs	100 μs
	Initial Phase Polarity	Alternates with each pulse	Alternates with each pulse
Net Charge (per pulse)		Nominally 0 μC @ 500Ω, zero net current	Nominally 0 μC @ 500Ω, zero net current
Maximum Phase Charge		20 μC @ 500Ω 20 μC @ 1000Ω	10 μC @ 500Ω 10 μC @ 1000Ω
Maximum Current Density (r.m.s.)		0.71 mA/cm^2 @ 500Ω	0.51 mA/cm^2 @ 500Ω
Maximum Average Current		4 mA @ 500 Ω	1.6 mA @ 500 Ω
Maximum Average Power Density		7 mW/cm^2 @ 500Ω	3.6 mW/cm^2 @ 500Ω

Quell includes a number of new features or technological characteristics, as listed below. These features and technological characteristics do not raise new questions of safety or effectiveness.

On-skin Timer

This timer tracks the duration of time that the device and electrode have been on the user's skin continuously. At 4 hours the device alerts the user by pulsing stimulation at 1 Hz for 1 minute. The purpose of this alert is to encourage the user to ventilate their skin to reduce the risk of skin irritation, and therefore this feature does not raise new questions of safety or effectiveness.

Auto-restart Timer

If enabled, this timer automatically restarts therapy 1 hour following the end of the previous therapy session. The user retains control over stimulation and can start or halt therapy at any time. This feature is a convenience and therefore does not raise new questions of safety or effectiveness.

Stimulation Lock

If the user has been recumbent for a certain period of time then the device will ignore button presses that initiate therapy or increase the stimulation intensity. The ability to decrease the intensity and halt stimulation is not affected. The purpose of this feature is to prevent stimulation due to unintentional actuation of the push-button while the user is sleeping; therefore this feature does not raise new questions of safety or effectiveness.

Sleep Settings

There are three sleep settings. These settings offer the user the convenience of automatically reducing stimulation while sleeping, and therefore do not raise new questions of safety or effectiveness.

Sleep Tracking

Quell tracks sleep duration and quality based on body movement measured using an embedded accelerometer. This information helps the user track the quantity and quality of their sleep patterns. The sleep tracking data are not linked with any disease or condition; nor are they intended for use in the diagnosis, mitigation, treatment, or prevention of sleep disorders or other related conditions. As such, the sleep-tracking feature is a low risk, general wellness function that does not raise new questions of safety or effectiveness.

Virtual Button

Stimulation may be initiated and halted, and stimulation intensity may be increased and decreased via a virtual button. The virtual button functionality was validated in system testing, and in a validation protocol designed to confirm that the virtual button is safe and effective as outlined in the FDA's "*Radio Frequency Wireless Technology in Medical Devices. Guidance for Industry and Food and Drug Administration Staff (August 14, 2013).*" The results of testing confirmed that the virtual button is safe and effective. Moreover, the user retains control over stimulation and can override virtual button control through the hardwired push-button. The user may also inactivate the virtual button by disabling Bluetooth communication on the device. For the reasons described above, the virtual button functionality does not raise new questions of safety or effectiveness.

Mobile App

Quell includes an optional mobile app that provides several convenience features. The app is not required to operate the device. Those features of the mobile app that relate to the control and function of the Quell device were validated in system testing. The mobile app does not raise new questions of safety or effectiveness because it is an optional feature, only permits functions included in the device

itself, i.e., it adds no new functionality to the Quell device, and validation testing confirms that the Quell device with the mobile app is as safe and effective as the predicate.

In summary, Quell has identical indications and similar technological characteristics as the cleared ASCEND device (K140333). The limited differences between the devices do not raise new types of safety or effectiveness questions. As a result, Quell is substantially equivalent to the cleared ASCEND device.

GUIDANCE DOCUMENT

The FDA's "Draft Guidance for Industry and Staff: Class II Special Controls Guidance Document: Transcutaneous Electrical Nerve Stimulator for Pain Relief Intended for Over the Counter Use (April 5, 2010)" addresses transcutaneous electrical nerve stimulators with product code NUH. The recommendations from the draft guidance document were taken into account in preparing this 510(k) submission. NeuroMetrix believes that the Quell device complies with the special controls as outlined in the draft guidance, thereby providing additional assurance of safety and effectiveness.

This 510(k) submission also considered recent agency guidance on wireless technology; namely "Radio Frequency Wireless Technology in Medical Devices. Guidance for Industry and Food and Drug Administration Staff (August 14, 2013)." Additional guidance documents considered included "Mobile Medical Applications, Guidance for Industry and Food and Drug Administration Staff (February 9, 2015)" and "General Wellness: Policy for Low Risk Devices, Draft Guidance for Industry and Food and Drug Administration Staff (January 20, 2015)."

NON-CLINICAL TESTING

Verification testing of Quell included electrical, mechanical and software tests to show that the device meets its target specifications over a range of operating and storage conditions. Validation and performance testing demonstrates that the device meets user needs as reflected in the functional specification.

Quell conforms to the following standards:

- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance 2005 (3rd Ed) plus Amendments 1:2006 and 2:2007
- IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2007)
- IEC 60601-1-6 Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral standard: Usability (3rd Ed) 2010-1
- IEC 62304:2006 Medical device software – Software life cycle processes
- IEC 60601-1-11:2010 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

CLINICAL TESTING

NeuroMetrix determined that bench and non-clinical testing were sufficient to demonstrate that Quell is as safe and effective as the predicate ASCEND device.

CONCLUSION

The verification, validation, and performance data presented in this 510(k) submission demonstrate that Quell is substantially equivalent to the predicate ASCEND device.