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

December 3, 2014

Prizm Medical, Inc.
Mr. Jim Johnson
CEO
1236 Doker Drive
Modesto, CA 95351

Re: K133502
Trade/Device Name: Prizm Medical 5000Z/Firefly
Regulation Number: 21 CFR 882.5890
Regulation Name: Stimulator, Nerve Transcutaneous, Over-The-Counter
Regulatory Class: Class II
Product Code: NUH
Dated: August 21, 2014
Received: November 05, 2014

Dear Mr. Johnson,

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, 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)*
K133502

Device Name
Prizm Medical 5000Z Firefly Transcutaneous Nerve Stimulator

Indications for Use *(Describe)*

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

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)*

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.

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"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

I. SUBMITTER

510(k) Owner: Prizm Medical, Inc.

Address: 1236 Doker Drive

Modesto, CA 95351

Phone number: 770-622-0933

Contact person: Jim Johnson, CEO

Date prepared: October 22, 2013

II. DEVICE

Trade name: Prizm Medical 5000Z/Firefly

Common name: Electrical Stimulator OTC TENS

Classification name: Stimulator, Nerve Transcutaneous, Over-The-Counter

Classification Number: 21 CFR 882.5890

Product Code: NUH

Classification: II

III. PREDICATE DEVICE

Predicate device(s): Prizm Medical 5000Z System (K033122)
Axelgaard Mfg. Co. Ltd. UltraStim Kit (K013532)
Hollywog, LLC The Pain Pilot (K120500)
Omron Healthcare, Inc. PM3030 (K110068)

IV. INDICATIONS FOR USE

The Prizm Medical 5000Z/Firefly TENS System is to be used for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (e.g., arm and/or leg), and low back due to strain from exercise or normal household and work activities.

V. DEVICE DESCRIPTION

The 5000Z/Firefly is a portable, single channel TENS device with two pre-programmed operational modes. It is powered by 2 standard AAA alkaline or rechargeable batteries. All operational modes produce the Prizm Medical Bi-Sourced waveform. The user

selects a pre-programmed mode by using the program buttons to select one of two program options. The user is able to adjust the intensity up or down. The 5000Z/Firefly is intended for Over-the-Counter sale. The 5000Z/Firefly battery icon on the LED will flash when the batteries need replacement.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Prizm Medical 5000Z/Firefly TENS System has the same indications for use as the predicate device. The functional technological characteristics are the same in that there are no changes to the output modes (waveforms) or programs for the 5000Z/Firefly compared to the 5000Z system. The differences between the 5000Z system and 5000Z/Firefly are an increase in voltage, and the user interface. The 5000Z system has a small LED display and membrane switches for controlling and displaying adjustable settings. The 5000Z/Firefly has a key mat style push button system and a larger LED screen controlling and displaying the adjustable settings.

Substantial Equivalence Matrix

Product Characteristics	**Subject Device** Prizm Medical, Inc. 5000Z / Firefly	**Predicate (K033122)** Prizm Medical, Inc. 5000Z™ System	**Predicate (K013532)** Axelgaard Mfg. Co. Ltd. UltraStim Kit	**Predicate (K120500)** Hollywog, LLC The Pain Pilot	**Predicate (K110068)** Omron Healthcare, Inc. PM3030
Power Source	Two “AAA” standard alkaline batteries or rechargeable	One “AAA” alkaline battery	One 9-volt alkaline battery	Two “AAA” standard alkaline batteries	Two “AAA” standard alkaline batteries
Number of Output Modes	2	2	5	4	3
Number of Output Channels	1 (twin peak, monophasic)	1 (twin peak, monophasic)	1 (Asymmetric biphasic)	1 (Asynchronous-biphasic)	1 (Asynchronous-biphasic)
Regulated Current / Voltage	Yes	Yes	Yes	Yes	Yes
Software/Firmware/ Microprocessor Control?	Yes	Yes	Yes	Yes	Yes
Automatic Shut Off	Yes	Yes	Yes	Yes	Yes
User Override Control	Yes	Yes	Yes	Yes	Yes
Indicator Display:					
On/Off Status	Yes	Yes	Yes	Yes	Yes
Low Battery	Yes	Yes	Yes	Yes	Yes
Volt/Current Level	Yes	Yes	Yes	No	Yes
Timer Rang (minutes)	Nonadjustable 30 min/ Nonadjustable 20 min	Nonadjustable 30 min/ Nonadjustable 20 min	Nonadjustable 30 min	Nonadjustable 30 min	Nonadjustable 30 min
Compliance with 21 CFR 898	N/A (no lead wires)	Yes	Yes	Yes	Yes
Weight	Approximately 1.8 oz. without battery	Approximately 2 oz. without battery	120g with battery	4.8 oz. w/ included battery	2.1 oz. w/ included battery
Size	3.75” x 2.0” x 1.0”	1.8” x 1.9” x 0.48”	10 cm x 6 cm x 2.1 cm	7.5” x 3.5” x0.7”	2.17” x 3.74” x 0.74”
Housing Material	ABS plastic	ABS plastic	Plastic	ABS plastic	ABS plastic
Waveform	Monophasic	Monophasic	Asymmetric biphasic	Asynchronous-biphasic	Asynchronous-biphasic
Shape	Twin peak	Twin peak	Asynchronous	Asynchronous	Rectangular
Maximum Output Voltage	200V	100V	40V	55V	35.4V
Maximum Output	0.384 mA	0.192 mA	80 mA	110 mA	4.4 mA

Substantial Equivalence Matrix

Product Characteristics	**Subject Device**	**Predicate (K033122)**	**Predicate (K013532)**	**Predicate (K120500)**	**Predicate (K110068)**
	Prizm Medical, Inc. 5000Z / Firefly	Prizm Medical, Inc. 5000Z™ System	Axelgaard Mfg. Co. Ltd. UltraStim Kit	Hollywog, LLC The Pain Pilot	Omron Healthcare, Inc. PM3030
Pulse Duration	100 (μsec)	100 (μsec)	260 (μsec)	120 – 240 (μsec)	Unspecified
Frequency / Hz	1 to 120Hz	1 to 120Hz	3 to 100Hz	5 to 100Hz	1 to 100Hz
Maximum Phase Charge	3.2 μC (500 Ω load)	3.0 μC (500 Ω load)	5.0 μC (500 Ω load)	Unspecified	133 μC (500 Ω load)
Maximum current density (500Ω)	0.0256 mA/cm2	0.0076 mA/cm2	1.81mA/area of electrode	0.12 mA/cm2	0.095 mA/cm2
Maximum Average Current (500Ω)	0.64 mA	0.12 mA	Unspecified	1.6 mA	3.5 mA
Maximum Average Power Density (500Ω)	5.12 mW/cm2	1.92mW/cm2	Unspecified	0.69mW/cm2	89mW/cm2
Phase duration	100 microseconds (μsec)	100 microseconds (μsec)	300 microseconds (μsec)	120-480 (μsec)	Unspecified
Output type	Constant voltage	Constant voltage	Constant current	Constant current	Constant current

VII. PERFORMANCE DATA

Non-clinical Testing:

The software verification has been carried out according to the FDA guidance for the content of premarket submissions for software contained in medical devices.

Verification of the Prizm Medical 5000Z/Firefly TENS System includes electrical and mechanical tests to show that the device meets its product specifications over a range of operating and storage conditions.

Validation testing for the Prizm Medical 5000Z/Firefly TENS System includes testing to show the device meets user needs according to marketing requirements.

Clinical Testing:

The Prizm Medical 5000Z/Firefly TENS System does not require clinical testing in order to determine substantial equivalence to the predicate unmodified device because the programs and electrical output characteristics of the two devices are the same.

VIII. CONCLUSION

Technological characteristics, features, specifications, materials and intended uses of the Prizm Medical 5000Z/Firefly TENS System are substantially equivalent to the predicate device(s). The electrical stimulation provided by the Prizm Medical 5000Z/Firefly TENS System is similar to the commonly employed TENS devices that have been cleared for marketing without prescription labeling. The engineering differences do not: **(1)** affect the intended use or (2) alter the fundamental scientific technology of the device. The non-clinical testing demonstrates that the Prizm Medical 5000Z/Firefly TENS System performs as well as the predicate device(s). There are no new safety or effectiveness issues concerning the new device.