August 30, 2019

ReliefBand Technologies LLC
Barbara Whitman
Vice President, Regulatory Affairs and Quality Assurance
220 Gibraltar Rd Ste 270
Horsham, Pennsylvania 19044

Re: K191547
Trade/Device Name: ReliefBand 1.5 and ReliefBand 2.0
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZJ
Dated: July 30, 2019
Received: August 1, 2019

Dear Barbara Whitman:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Robert Kang, PharmD
Acting Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191547

Device Name
ReliefBand 1.5 and ReliefBand 2.0

Indications for Use *(Describe)*
ReliefBand(R) is indicated for use in the treatment of nausea, vomiting and retching associated with physician-diagnosed migraine, hangover, anxiety, motion sickness, chemotherapy and morning sickness from pregnancy. ReliefBand is also indicated as an adjunct to antiemetics in reducing postoperative nausea. For over the counter use.

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.

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510K Summary
K191547

Submitter Information

Applicant: Reliefband® Technologies LLC
220 Gibralter Road, Suite 270
Horsham, PA 19044

Phone: 877-735-2263 Ext 122

Contact: Barbara Whitman

Vice President of Regulatory Affairs and Quality Assurance

Date Prepared: July 30, 2019

Device Classification

Trade name: ReliefBand® 1.5, ReliefBand® 2.0

Common Name: Nerve Stimulation Therapy Device

Classification Name: Transcutaneous electrical nerve stimulator for pain relief (21 CFR 882.5890)

Product Code: GZJ

Device Classification: Class II

Predicate Devices: ReliefBand® 1.5 (K173233) and ReliefBand® 2.0 (K182960)

Description of the Device

ReliefBand® models 1.5 and 2.0 are battery-powered non-invasive digital therapeutic devices that are worn on the wrist like a watch. They are indicated for the over the counter use in the relief of mild to moderate nausea and retching associated with physician-diagnosed migraine, hangover, anxiety, motion sickness, chemotherapy and morning sickness associated with pregnancy as an adjunct to antiemetics in reducing mild to moderate postoperative nausea.

ReliefBand 1.5 and 2.0 include two electrical contacts on the back of the device (ReliefBand 1.5) or on the clasp (ReliefBand 2.0), which must be placed firmly against the underside of the wrist at the P6 location (approximately two fingers breadth above the distal skin crease of the wrist joint, between the tendons of the palmaris longus and flexor carpi radialis muscles). The electrodes provide relief of nausea and vomiting through electrical stimulation of the median nerve on the ventral side of the patient's wrist.

The ReliefBand device has a user display that includes a five-level (ReliefBand 1.5) or 10-level (ReliefBand 2.0) LED that indicates the signal intensity. The patient can easily select the pulse amplitude of the electrical impulse and control the intensity of the stimulation via a pushbutton

located on the face of the devices. A low battery indicator LED is also included on the face of the devices. ReliefBand 1.5 uses disposable batteries while ReliefBand 2.0 has a lithium-ion rechargeable battery. A fully charged battery will last for up to 18 hours of continuous use at the mid-power level or below.

Indications for Use

ReliefBand is indicated for use in the treatment of nausea, vomiting and retching associated with physician-diagnosed migraine, hangover, anxiety, motion sickness, chemotherapy and morning sickness from pregnancy. ReliefBand is also indicated as an adjunct to antiemetics in reducing postoperative nausea. For over the counter use.

Technical Characteristics

The subject and the predicate ReliefBand devices are identical. Only the wording in the indications for use has changed. The are no changes in technical characteristic between the predicate and the subject devices. The differences between the subject ReliefBand and the predicate device do not raise new questions about the safety or effectiveness of the device.

Item	**ReliefBand® 1.5 and 2.0 (Predicate Devices)**	**ReliefBand® 1.5 and 2.0 (Subject Devices)**
Indications for Use	Reliefband® is a digital therapeutic device indicated for use in the treatment of nausea, retching and vomiting due to motion sickness, morning sickness associated with pregnancy, and chemotherapy. Reliefband® is also indicated as an adjunct to antiemetic therapy in reducing postoperative nausea. ReliefBand 2.0 is indicated for use in the treatment of nausea, retching and vomiting due to motion sickness, chemotherapy and morning sickness associated with pregnancy. ReliefBand 2.0 is also indicated as an adjunct to antiemetics in reducing postoperative nausea.	Reliefband® is indicated for use in the treatment of nausea, vomiting and retching associated with physician diagnosed migraine, hangover, anxiety, motion sickness, chemotherapy and morning sickness from pregnancy. ReliefBand is also indicated as an adjunct to antiemetics in reducing postoperative nausea. For over the counter use.
Size ReliefBand 1.5 ReliefBand 2.0	 Teardrop shape, 3.81Wx5.08Lx1.14H cm Rectangular shape, 1.45Wx2.35Lx0.41H cm	 Identical for ReliefBand 1.5 Identical for ReliefBand 2.0
Weight ReliefBand 1.5 ReliefBand 2.0	 Approximately 34 grams Approximately 50 grams	 Identical for ReliefBand 1.5 Identical for ReliefBand 2.0
Operating Temperature ReliefBand 1.5 ReliefBand 2.0	 10°C to 45°C (50°F to 113°F) ±18% output tolerance at operating extremes	 Identical
User Controls ReliefBand 1.5 ReliefBand 2.0	 One Push Button: On/Off/Intensity Two Push Buttons: On/Off (1), Intensity (2)	 Identical for ReliefBand 1.5 Identical for ReliefBand 2.0
Operating Modes	ON/OFF/Set intensity level	Identical
Interactive Display		

ReliefBand 1.5 ReliefBand 2.0	Five flashing LED setting indicators (green), 2 second flash period during normal operation. One flashing low battery LED indicator (red), 4 second flash period alternating with setting LED when in Low Battery operation. Ten diagonal blue LED bars indicate therapy power level. Four circular blue LED segments indicate battery charge level.	Identical for ReliefBand 1.5 Identical for ReliefBand 2.0
Display Face Location ReliefBand 1.5 ReliefBand 2.0	 Ventral side Dorsal Side	 Identical for ReliefBand 1.5 Identical for ReliefBand 2.0
Output Waveform	Asymmetric biphasic pulses. Ramp up, constant and ramp down phases.	Identical
Peak pulse Amplitude ReliefBand 1.5 ReliefBand 2.0	 Five discrete levels between 10-40 mA (nominal), set by intensity selection; nominally constant current, +/-10% at nominal conditions Ten discrete levels between 8-40 mA (nominal), set by intensity selection; nominally constant current, +/-10% at nominal conditions	 Identical for ReliefBand 1.5 Identical for ReliefBand 2.0
Pulse frequency	Fixed at 31 Hz (32 millisecond period).	Identical
Pulse width	Fixed at 350 milliseconds.	Identical
Amplitude modulation cycle	Single cycle	Identical
Maximum Charge Delivered (500 Ω load)	Approximately 3.1 microcoulombs (max. 3.56 microcoulombs including 15% output tolerance)	Identical
Electrodes ReliefBand 1.5 ReliefBand 2.0	 Two gold-plated copper, nickel or zinc Two hypoallergenic surgical grade (316L) stainless steel contacts	 Identical for ReliefBand 1.5 Identical for ReliefBand 2.0
Device Status Indicators ReliefBand 1.5 ReliefBand 2.0	 Five separate green flashing LEDs indicate 5 intensity levels. Selection of the intensity level is performed via a pushbutton located on the user display. A sixth blinking LED is used to display the low battery indicator. Ten Intensity level LEDS are arranged in a single line. Selection of the intensity level is performed via a pushbutton on the edge of the face. Battery charge indicator provides 4 charge levels and a red blinking low power warning LED.	 Identical for ReliefBand 1.5 Identical for ReliefBand 2.0
Power		

ReliefBand 1.5 ReliefBand 2.0	3V, CR2025 Lithium-ion coin cells only, replaceable. Rechargeable 40 mA Li-Ion Polymer - IEC62133 standard. Not replaceable.	Identical for ReliefBand 1.5 Identical for ReliefBand 2.0
Regulation of Stimulus Output with Decreasing Battery Voltage	Regulation is ± 5% of nominal output. Device stops stimulation when regulation cannot be maintained (device turns itself off).	Identical
Battery Life ReliefBand 1.5 ReliefBand 2.0	 18 hours continuous or intermittent use with two 3V CR2025 Approximately three years/ 500 charge cycles.	 Identical for ReliefBand 1.5 Identical for ReliefBand 2.0
Low Battery Warning ReliefBand 1.5 ReliefBand 2.0	 Low battery indicator flashes when approximately 10% of battery life remains. When battery level registers 15% or less, a single LED segment will switch from static blue to flashing red.	 Identical for ReliefBand 1.5 Identical for ReliefBand 2.0
Wrist Band ReliefBand 1.5 ReliefBand 2.0	 Contains latex Latex-Free	 Identical for ReliefBand 1.5 Identical for ReliefBand 2.0

Performance Specifications

The performance specifications for the applicant ReliefBand devices are identical, and thus substantially equivalent, to the predicate devices.

Basis for Determination of Substantial Equivalence

Substantial equivalence was determined on the basis that there have been no changes in the physical device, technology, mechanism of action or intended use. Device modifications include only the clarified intended use, which includes an additional anticipated source of nausea (physician-diagnosed migraine) that Reliefband is intended to treat. These changes do not impact the safety of efficacy of the ReliefBand 1.5 or ReliefBand 2.0 devices.