June 21, 2019

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

Re: K182960
Trade/Device Name: 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: May 22, 2019
Received: May 22, 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,

Pamela Scott
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)*
K182960

Device Name
ReliefBand 2.0

Indications for Use *(Describe)*
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.

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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510(k) SUMMARY
K182960
ReliefBand 2.0

Submitter Information

Applicant: Relief band® 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: October 15, 2018

Device Classification

Trade name: 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 Device: ReliefBand® 1.5, K173233

Description of the Device

ReliefBand® 2.0 is a rechargeable, non-invasive digital therapeutic device that is worn on the wrist like a watch. It is a non-invasive device that is indicated for the over the counter use in the relief of mild to moderate nausea and vomiting associated with chemotherapy, motion sickness, mild to moderate nausea and vomiting associated with pregnancy, and as an adjunct to antiemetics in reducing mild to moderate postoperative nausea.

ReliefBand 2.0® includes a hypoallergenic band with two electrical contacts on the clasp end of the band. The two contacts 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 in the wristband 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 incorporates a ten-segment linear LED that is used to display the intensity level. 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 edge of the device. Battery charge level is indicated by a separate four-segment circular LED. A fully charged battery will last for approximately 18 hours of continuous use at the mid-power level or below.

Indications for Use

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.

Technical Characteristics
A comparison of the technological characteristics of the ReliefBand® 2.0 and the predicate device ReliefBand® 1.5 has been performed. The results of the comparison demonstrate that the ReliefBand® 2.0 device is substantially equivalent to the marketed predicate device. The differences between the ReliefBand® and the predicate device do not raise new questions about the safety or effectiveness of the device.

Basis for Determination of Substantial Equivalence
Substantial equivalence was determined on the basis that there have been no changes in the technology, mechanism of action or intended use. Device modifications include relocation of the electrodes from the back of the device face to the clasp end of the wrist band, changes in the size, shape and aesthetic appearance of the casing, a simpler and more streamlined user interface and a power source change from disposable to rechargeable batteries. There is a new user interface that provides 10 increments of intensity from 8 to 40 mA where there were previously 5 increments from 10 to 40 mA. These changes do not impact the safety of efficacy of the ReliefBand® 2.0 device.

Item	ReliefBand 1.5	ReliefBand 2.0	Comments
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 post-operative 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	Similar
Size	Teardrop shape, 3.81W x 5.08L x 1.14 H cm	Rectangular shape, 1.45 W x 2.35 L x 0.41 H cm	Does not affect safety and effectiveness
Weight	Approximately 34 grams	Approximately 50 grams	Does not affect safety and effectiveness

Operating Temperature	10°C to 45°C (50°F to 113°F) ±18% output tolerance at operating extremes	Same	Identical
User Controls	Push Button	Two Push Buttons: On/Off and Intensity Down/Up	Does not affect safety and effectiveness
Operating Modes	OFF ON/Set intensity level	Same	Identical
Interactive Display	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	Blue LED logo pulsing means device is providing therapy. Ten diagonal blue LED bars indicate therapy power level. Four circular blue LED segments indicate battery charge level.	Does not affect safety and effectiveness
Display Face Location	Ventral side	Dorsal side	Does not affect safety and effectiveness
Output Waveform	Asymmetric biphasic pulses. Ramp up, constant and ramp down phases.	Same	Identical
Peak pulse amplitude	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	Similar
Pulse frequency	Fixed at 31 Hz (32 millisecond period).	Same	Identical
Pulse width	Fixed at 350 milliseconds.	Same	Identical

Amplitude modulation cycle	Single cycle	Same	Identical
Maximum Charge Delivered (500 Ω load)	Approximately 3.1 microcoulombs (max. 3.56 microcoulombs including 15% output tolerance)	Same	Identical
Electrodes	Two gold-plated copper, nickel or zinc	Two hypoallergenic surgical grade (316L) stainless steel contacts	Previously cleared material. Does not adversely impact safety and/or effectiveness
Device Status Indicators	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	Does not affect safety and effectiveness
Power	3V, CR2025 Lithium coin cells only, replaceable.	Rechargeable 40 mA Li-Ion Polymer (max capacity 50 mA)	Conforms to IEC 62133 standard.
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).	Same	Identical

Battery life	150 hours continuous or intermittent use when two 3V CR2025 used.	Approximately three years or 500 charge cycle	Does not adversely impact safety and/or effectiveness
Low battery warning	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	Does not adversely impact safety and/or effectiveness
Wrist band	Contains latex	Latex free	Conforms to ISO 10993 standard

Performance Specifications

The performance specifications for the ReliefBand® 2.0 device are substantially equivalent to the predicate device. ReliefBand 2.0 was tested to the following standard:

- ISO 14971: Medical Devices – Application of Risk Management to Medical Devices

Conclusion:

A comparison of the technological characteristics of the ReliefBand® 2.0 and the predicate device ReliefBand® 1.5 was performed. The results of the comparison demonstrate that the ReliefBand® 2.0 device is substantially equivalent to the marketed predicate device.