510(k) Summary
K173233

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Trade name: ReliefBand® Device

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

Manufacturer and Distributor: ReliefBand Technologies
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Predicate Devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
(PRIMARY PREDICATE) ReliefBand® Device Models RB-DL, RB-EL, and RB-RL (OTC)	Woodside Biomedical, Inc.	K020180	March 21, 2002
ReliefBand® Device Models WB-2L, WB-6L, and WB-RL (Rx)	Woodside Biomedical, Inc.	K994387	March 16, 2000

Description of the Subject Device

The ReliefBand® 1.5 is a non-invasive device that is indicated for the over the counter use in the relief of mild to moderate nausea, retching 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. This device was originally marketed under its predicate name of Reliefband RB-EL (K020180) when owned by Woodside Biomedical, Inc. The devices are technologically identical. The same contract manufacturer has made this device for decades.

Exactly like its predicate, the Reliefband 1.5 is contained within a wristband, and provides relief of nausea, retching and vomiting through electrical stimulation of the nerves on the ventral side of the patient's wrist. The device can be worn on the ventral or palmar (i.e., inside) surface of either or both wrists, 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 ReliefBand® 1.5 has a user display that incorporates five blinking LEDs which are used to identify the intensity level (5 discrete LEDs, one for each intensity level), so that the patient can easily select the desired stimulation. Selection of the intensity level is performed via a pushbutton located on the user display, which controls the peak pulse amplitude of the electrical impulse and thereby determines the intensity of the stimulation. A sixth blinking LED is used to display the low battery indicator.

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.

Technical Characteristics

A comparison of the technological characteristics of the ReliefBand® 1.5 Device family and the predicate devices has been performed. The results of the comparison demonstrate that the ReliefBand® 1.5 is substantially equivalent to the marketed predicate devices. The differences between the ReliefBand® 1.5 and the predicate models are based solely on marketing changes and do not affect the safety or effectiveness of the device. The Reliefband® 1.5 is technologically identical to its previously cleared predicate device Reliefband® RB-EL. (Please see table below).

Technical Characteristics - Substantial Equivalency Table

Performance Characteristic	Rx Predicate Device (K994387)	OTC Predicate Device RB-xL (K020180)	K173233 OTC ReliefBand® 1.5
Indications for Use	The ReliefBand NST Device is indicated for use in the treatment of nausea and vomiting (NV) due to chemotherapy, motion sickness, and pregnancy. The ReliefBand NST Device is indicated as an adjunct to antiemetics in reducing postoperative nausea (PON)	The ReliefBand Devices are indicated for over the counter use in the relief of nausea and vomiting (NV) due to motion sickness and for relief of mild to moderate nausea and vomiting associated with pregnancy	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.
Size	Teardrop shape (approximately 1.5" by 2" by 0.45" thick enclosure)		
Weight	Approximately 1.2 ounce (34 grams)		
Operating Temperature	10°C to 45°C (50°F to 113°F) (±18% output tolerance at operating extremes)		
User Controls	Single push button (membrane keypad)		
User Displays	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		
Operating Modes	OFF ON/Set intensity level		

Performance Characteristic	Rx Predicate Device (K994387)	OTC Predicate Device RB-xL (K020180)	K173233 OTC ReliefBand® 1.5
Output Range (Peak pulse current at nominal, 500 ohm load)	Five discrete levels between 10 mA (± 15%) – 40 mA (± 15%).		
Output Waveform Characteristics (At nominal, 500 Ohm load)	Asymmetric biphasic pulses. Ramp up, constant and ramp down phases.		
Maximum Charge Delivered (Setting 5, charge per pulse at nominal, 500 ohm load)	Approximately 3.1 microcoulombs (max. 3.56 microcoulombs including 15% output tolerance)		
Maximum Output Voltage (open circuit, no load)	110 Volts		
Output Channels	Two captive electrodes.		
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).		
Battery Life: (Setting 3 at nominal)	150 hours continuous or intermittent use when two 3V CR2025 used. Low battery indicator flashes when approximately 10% of battery life remains.		

Performance Data

The performance data indicate that the ReliefBand® 1.5 device family is substantially equivalent to the predicate devices cleared to market via 510(k) #s: K994387 and K020180.

Basis for Determination of Substantial Equivalence

Substantial equivalence was determined on the basis that there have been no changes in the mechanism of action, intended use and safety and effectiveness. The technology of the subject device has remained identical to that of its predicates and is therefore substantially equivalent to the predicate devices.