K060669

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OCT 13 2006

Healthonics

The Biophysics Health Company™

510(k) Summary:

510(k) Owner:	Healthonics, Inc. 903 Main Street South New Ellenton, SC 29803
Contact Person:	James W. Kronberg Chief Engineer Phone 803-652-2354 Fax 775-251-0023
Date Prepared:	March 10, 2006 – Revised September 13, 2006
Device Name:	**MedRelief ST ("Sub-Threshold") Series**, consisting of models **ST-100, ST-150, ST-200** and **ST-300**.
Common or Usual Name:	TENS device.
Classification Name:	Transcutaneous Electrical Nerve Stimulator for Pain Relief. 21 CFR 882.5890, Class II, Product Code 84GZJ (prescription) or Stimulator, Electrical, Transcutaneous, for Arthritis. 21 CFR 882.5890, Class II, Product Code NYN (prescription).
Predicate Devices:	Healthonics **MedRelief® SE-50** for acute and chronic pain indications (K030998). Bionicare **Model BIO-1000** for osteoarthritis (K030332) and rheumatoid arthritis (K983228) indications.

Description of the Device:

The **MedRelief® ST Series™**, consisting of models **ST-100**, **ST-150, ST-200** and **ST-300**, is designed to provide subthreshold electrical stimulation for acute and chronic pain, including pain from osteoarthritis and rheumatoid arthritis, in a single compact, lightweight and user-friendly package. "Subthreshold" stimulation does not normally cause sensation or muscle contraction, but acts at a cellular level to relieve pain.

Each device in the ST Series is comprised of the following main components:

- A power section consisting of battery, switch, test and conditioning components;
- A dosing timer, initialized at power-on and providing a choice of treatment times;
- A control oscillator, providing pulse-burst timing;
- A pulse oscillator, providing timing for individual pulses; and
- An output section, providing filtering, DC blocking and intensity control.

While some components are digital, all functions are hard-wired and there is no microprocessor or software used. Output is by means of lead wires and skin-contact electrodes already commercially available and legally sold by others.

The member devices in the **ST Series™** differ only in the complexity of their controls and number of physician or user options which each model offers.

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Indications and Intended Use:

- Relief of chronic intractable pain. (All models);
- Adjunctive treatment of post-surgical or post-traumatic acute pain. (All models);
- Adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee. **(ST-150, ST-200** and **ST-300 only)**.
- Adjunctive therapy in reducing the level of pain, and stiffness associated with pain, from rheumatoid arthritis of the hand. **(ST-150, ST-200** and **ST-300 only)**.

The indications are the same as for the predicate devices listed. All units are for prescription use only. The **ST-100** is a simplified unit meant for home use, with one output channel and a minimal set of signal options, closely similar to the **SE-50** predicate device. Other devices in the **ST Series™** are meant for a wider range of indications by including a signal modeled on that of the Bionicare **BIO-1000** predicate device. The **ST-150** is otherwise identical with the **ST-100.** The **ST-200** offers two output channels and more user options. The **ST-300** offers four channels, even more options, and is meant for use in a clinical setting only.

Technological Characteristics:

The technological characteristics of the **MedRelief® ST Series™** are the same as those of the predicate devices. Each device is battery-powered with no provisions for line power or AC adapters. Each uses solid-state electronics to produce trains of subthreshold electrical pulses, at frequencies within the human audible range (~20 Hz to ~20 KHz), which are applied to the body through self-adhesive or gelled electrodes placed on the skin. Pulses have zero net charge and may be applied either continuously, or divided into pulse bursts alternating with quiet periods. All signal characteristics comply with the safety requirements of AAMI NS4.

Comparison of Features of **MedRelief® ST Series™** Models

(s) – user switch selected. (c) – user adjustable through continuous range.

Characteristic or Feature	ST-100	ST-150	ST-200	ST-300
Intended use	Intractable chronic, postsurgical / posttraumatic acute and arthritis-related pain.			
Intended sale	Prescription only			
Number of output channels	1		2	4
Pulse frequency	700, 1800 or 4150 Hz (s)	100, 700 or 4150 Hz (s)	100, 230, 700,1800, 4150 Hz or 12 KHz (s)	100 Hz to 20 KHz (c)
Pulse (short phase) length	1/7 of long phase or 20 microseconds, whichever is greater			
Burst frequency	15 Hz in pulse burst mode; N/A in continuous mode.			
Burst duty cycle	15% or 100%* (s)		5% up to 100%* (c)	
Timer	None (runs whenever turned on)		30 min., 8 hrs or cont. (s)	
Dimensions, in.	2.5 x 2.1 x 0.63		3.5 x 2.5 x 1	7 x 5 x 2.5
	MedRelief miniature 9V lithium			
Weight including battery	1.7 oz.		2.5 oz.	8 oz.
Charger, AC cord or adapter?	None			

* Burst duty cycle of 100% = continuous operation.

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Comparison of General and Technical Characteristics to Predicates.

Electrical output measurements assume a 500-ohm load. Timing values cited below are accurate to ±20% or 10 microseconds, whichever is larger. Other cited values are accurate to ±20% unless otherwise stated.

For conciseness, (10), (15), (20) and (30) refer to the **ST-100, ST-150, ST-200** and **ST-300** respectively. "Same" plus one or more of these labels in a Predicate column means "same as in the indicated **ST Series™** device(s)," while without a label it means "same for all." See also notes 1-3 at the bottom of the table.

Unit Characteristic	**Proposed Device**	Predicate #1.	Predicate #2
Device name and model	**MedRelief® ST Series (ST-100, ST-150, ST-200 and ST-300)**	**MedRelief® SE-50** (in **SE Series**).	**BioniCare® Stimulator, Model BIO-1000™**
Manufacturer	Healthonics, Inc. 903 Main Street South New Ellenton, SC 29803	Same.	BioniCare Medical Technologies,Inc. 47 R. Loveton Circle Sparks, MD 21152
510(k) number	To be assigned	K030998	K030332, K983228
Procode	GZJ, NYN	GZJ	NYN
Intended Use (indications; abbreviated, see full list above.)	1. Chronic intractable pain. 2. Post-surgical/post-traumatic acute pain. 3. Pain/symptoms from osteoarthritis of the knee. 4. Pain/stiffness from rheumatoid arthritis of the hand.	Same as #1 and #2 for proposed device.	Same as #3 and #4 for proposed device
Number of output modes	One: subthreshold TENS.	Same.	Same.
Number of output channels.	One (10, 15), two (20), or four (30).	One.	Version A: one. Version B: two.
Pulse shape	Rectangular to exponential, depending on pulse length and charge balancing time chosen.	Same.	One phase exponential, other phase rectangular.
Mono- or biphasic	Biphasic	Biphasic	Biphasic (note 1)
Maximum instantaneous current	8.62 mA	Same	24 mA
Maximum time averaged current	2.27 mA (2.71 mA, note 2)	Same	2 mA
Maximum phase charge	12.4 μC at 100 Hz; 1.87 μC at 700 Hz (note 2)	1.87 μC at 700 Hz (note 2)	20 μC at 100 Hz
Maximum current density at electrode	0.41 mA/sq.cm. (note 2)	Same	0.14 mA/sq.cm. (note 3)
Maximum power density at electrode	0.133 mW/sq.cm. (note 2)	Same	0.83 mW/sq.cm. (note 3)
Regulated current or regulated voltage?	Regulated current.	Same.	Regulated voltage.
Software/ firmware/ /microprocessor control?	No	No	No in Version A; yes in Version B.
Housing materials and construction.	Flame-retardant ABS plastic.	Same.	Flame-retardant Cycolac plastic
Accessories:			
1. Electrodes.	Pregelled reusable electrode, 25 cm^2 gel area, with "pigtail" wire connection. For 100 Hz use (15, 20, 30), same but with 175 cm^2 gel area.	Pregelled reusable electrode, 25 cm^2 gel area, with "pigtail" wire connection.	BioniCare special design, metal mesh, 170-176 cm^2 gel-coated area.
2. Conductive medium (gel),	None	None	Spectra 360

3. Electrode lead wires.	2 mm pin joined to 2mm socket by flexible wire	Same.	Semicustom wires, snap connectors
4. Batteries.	9V lithium batteries: miniature semicustom (10, 15, 20) ; standard rectangular (30).	Same (10, 15, 20)	Self-contained rechargeable battery.
5. Battery charger, if used.	None.	None.	Plug-in wall transformer type

Note 1. BioniCare claims monophasic pulses, but Healthonics scope measurements show the second phase is not completely suppressed so the BioniCare pulses are actually biphasic.

Note 2: Taken under conservative worst-case conditions including any single-component failure.

Note 3. Healthonics measured from predicate device or calculated from information in predicate's 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 2006

Healthonics, Inc.
% Mr. James W. Kronberg
Chief Engineer
903 Main Street South
New Ellenton, South Carolina 29809

Re: K060669
Trade Name: MedRelief ST ("Sub-Threshold") Series consisting of model numbers ST-100. ST-150, ST-200, and ST-300
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Codes: GZJ, NYN
Dated: September 13, 2006
Received: September 14, 2006

Dear Mr. Kronberg:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) number (if known): K060669

Device Name: **MedRelief ST ("Sub-Threshold") Series**, consisting of model numbers **ST-100**, **ST-150, ST-200** and **ST-300**.

Indications for Use.

For Prescription Use Model **SE-100**:

- Relief of chronic intractable pain.
- Adjunctive treatment of post-surgical or post-traumatic acute pain.

For Prescription Use Models **ST-150, ST-200** and **ST-300**:

- Relief of chronic intractable pain.
- Adjunctive treatment of post-surgical or post-traumatic acute pain.
- Adjunctive therapy in reducing the level of pain associated with osteoarthritis of the knee.
- Adjunctive therapy in reducing the level of pain from rheumatoid arthritis of the hand.

Prescription Use ✓ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart D)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060669