K030998

OCT 1 0 2003

510(k) SUMMARY.

MedRelief SE ("Structured Energy") Series
(consisting of models SE-50, SE-100, SE-200 and SE-300)

Common/Classification Names:
Microcurrent TENS Device, 21 CFR 882.5890
Interferential stimulator, 21 CFR 890.5850
Powered muscle stimulator, 21 CFR 890.5850

Healthonics, Inc.
903 Main Street South
New Ellenton, SC 29809
Establishment Registration #1067052

Contact: James W. Kronberg
Prepared: March 27, 2003

A. LEGALLY MARKETED PREDICATE DEVICES.

Devices in the **MedRelief SE Series™** are substantially equivalent:
(1) in powered muscle stimulation functions to the Microstim J-1304D, made by Nisha Communications Industries, Light Industrial Area, Jodhpur 342003 India, which was cleared for marketing by the FDA on July 13, 1998 as K980040;
(2) in interferential stimulation functions to the IF-II Model 7200, made by Medical Devices, Inc., 833 Third Street Southwest, St. Paul, MN 55112-3483, which was cleared for marketing by the FDA on November 6, 1992 as K923914; and,
(3) in microcurrent TENS stimulation functions to the original MedRelief device, made by Healthonics, Inc., 903 Main Street South, New Ellenton, SC 29803, which was cleared for marketing by the FDA on Feb. 21, 2001 as K003507, and to the Home Microcurrent HMC, also made by Medical Devices, Inc., which was cleared for marketing by the FDA on March 14, 1994 as K935132.

B. DEVICE DESCRIPTION.

The **MedRelief SE Series™** provides a selection of both high-level and subthreshold electrotherapeutic modes in a compact, lightweight and user-friendly package. "Subthreshold" as used here means electrical stimulation not strong enough to cause nerve depolarization or muscle contraction, but still active at a cellular level, as in microcurrent TENS. Healthonics' proprietary version of subthreshold stimulation has been named Structured Energy™.

Devices in the **MedRelief SE Series™** provide combinations of these stimulation modes as follows:

Model number	Includes:	muscle stimulation	interferential stimulation	Structured Energy™	Controls
SE-300		X	X	X	Rotary
SE-200		X *	X *	X	Rotary
SE-100		---	---	X	Rotary
SE-50		---	---	X	Recessed

* - Output provided over reduced intensity range.

Models **SE-200™** and **SE-300™** provide all three stimulation modes, while Models **SE-50™** and **SE-100™** are miniaturized, single-mode Structured Energy™-only versions. All devices are completely powered by 9-volt batteries, without provisions for line power or AC adapters. All devices are single-channel only.

All **SE Series™** devices produce trains of brief electrical pulses which are applied to the body through self-adhesive electrodes placed on the skin. Pulses recur at a nominal 4150 Hz and may be either 30 microseconds or 120 microseconds long. These pulses form a carrier wave which may then be modulated by one of three different envelopes, yielding respectively Structured Energy™, muscle stimulation, or premodulated interferential stimulation. Envelope frequencies range from 0.25 Hz to 130 Hz, depending on the mode being used.

All functions for a particular mode are preset, and accessed through a single rotary switch which also turns the device on and off. In the **SE-200™** and **SE-300™**, a second rotary switch provides intensity control. In the **SE-100™**, all control functions are integrated into a single rotary switch, while in the **SE-50™** this switch is replaced by two recessed, miniature slide switches.

While the **MedRelief SE Series™** incorporates some ancillary digital components such as frequency dividers, its primary functioning is analog, with all

digital functions hard-wired. Since there is no microprocessor, no software is needed.

C. INTENDED USE.

Since the **MedRelief SE Series™** is a family of devices with differing functions, only those indications which the FDA has traditionally approved for the corresponding device types are sought.

For the **SE-50™** and **SE-100™**, which include only subthreshold stimulation substantially equivalent to subthreshold TENS devices previously cleared by the FDA, the indications sought are:

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

For the **SE-200™** and **SE-300™**, which include powered muscle stimulation as well as interferential and subthreshold stimulation, the following additional indications are sought:

* Relaxation of muscle spasms.
* Prevention or retardation of disuse atrophy
* Muscle re-education
* Increasing local blood circulation
* Maintaining or increasing range of motion
* Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

D. SUBSTANTIAL EQUIVALENCE SUMMARY.

The **MedRelief SE Series™** is a family of medical devices, having the same indications for use, target populations, and technological characteristics as the legally marketed predicate devices. This premarket notification has described the characteristics of the **MedRelief SE Series™** in sufficient detail to assure substantial equivalence.

E. TECHNOLOGICAL CHARACTERISTICS.

Both new and predicate devices employ electronic circuitry to produce electrical output waveforms at closely comparable voltage and current levels and with closely comparable waveforms and timing. The **MedRelief SE Series™** is primarily analog, with some hard-wired digital functions but no microprocessor and thus no software.

F. TESTING.

Healthonics has carried out design and performance testing to address the following issues:

(1) Performance testing for the purpose of addressing the points in the FDA guidance document, "Guidance Document for Powered Muscle Stimulator 510(k)'s," dated June 9, 1999.

(2) Electrical safety. The **SE Series™** was designed to comply with UL-2601 and will be tested to this standard by an independent test laboratory before marketing.

(3) Electromagnetic compatibility. The **SE Series™** was designed to comply with EN 60601-1-2, May 1993. However, the FDA guidance document exempts powered muscle stimulators from compatibility requirements unless specific claims of compatibility are made. Since Healthonics makes no such claims, and since no other output mode exceeds muscle stimulation in voltage, current or power, Healthonics believes that the **SE Series™** is also exempt from this requirement.

(4) Conformance to NS4-1985. The **SE Series™** was designed to comply with applicable requirements of ANSI/AAMI NS4-1985, as supported by performance testing.

G. CONCLUSIONS.

In summary, this pre-market submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food, Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2003

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

Re: K030998
Trade/Device Name: MedRelief SE ("Structured Energy") Series™, Models SE-50, SE-100, SE-200 and SE-300
Regulation Number: 21 CFR 890.5850 and 21 CFR 882.5890
Regulation Name: Powered muscle stimulator and Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: IPF, GZJ, LIH
Dated: August 4, 2003
Received: August 5, 2003

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE.

510(k) number (if known) K030998

Device Name: **MedRelief SE ("Structured Energy") Series**, consisting of model numbers **SE-50**, **SE-100**, **SE-200** and **SE-300**.

Indications for Use:

The **MedRelief SE-50** and **SE-100**, and the **MedRelief SE-200** and **SE-300** in subthreshold and interferential modes, are intended for the following indications:

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

The **MedRelief SE-200** and **SE-300** in muscle stimulation mode are intended for the following indications:

- Relaxation of muscle spasms.
- Prevention or retardation of disuse atrophy.
- Muscle re-education.
- Increasing local blood circulation.
- Maintaining or increasing range of motion
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis (**SE-300** only).

For the **SE-200** and **SE-300** in muscle stimulation mode, the lowest three intensity settings may not provide effective muscle contractions to achieve the indications for use, especially when applied to large muscles or muscle groups. These settings are provided so that the intensity may be ramped up slowly for improved user comfort.

(Please do not write below this line - continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

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

510(k) Number K030998

Prescription Use ____ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)