

510(k) SUMMARY
Bionicare® Stimulator System, Model BIO-1000™
September 14, 1998

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA) and 21 C.F.R § 807.92. The information provided in the 510(k), premarket notification was in accordance with 21 C.F.R § 807.87 and the SMDA.

1.0 Submitter of 510(k) and Manufacturer

Murray Electronics
260 Schilling Circle
Hunt Valley, MD 21031

Attention: Kent C. Hoffman
Telephone: 410 771-0380 extension 231
Facsimile: 410 771-5576

2.0 Name of Device

2.1 Trade/Proprietary Name

Bionicare® Stimulator System, Model BIO-1000™

2.2 Common/Usual Name

TENS (Transcutaneous Electrical Nerve Stimulator)

2.3 Classification Name

Transcutaneous electrical nerve stimulator for pain relief (21CFR§ 882.5890, class II).

3.0 Identification of Predicate Device

Bionicare® Stimulator System, Model BIO-1000™
Murray Electronics
510(k) Number K971437, July 22, 1997

4.0 Device Description

The Bionicare® Stimulator System, Model BIO-1000™ is a rechargeable battery operated TENS stimulator that utilizes a voltage regulated output circuit to generate a spike-shaped pulse with an adjustable amplitude of 0-12 volts peak and repeating at a single fixed

frequency of 100 ± 5 Hertz. Electrodes are applied to the hand and arm using a standard electrode gel, Spectra 360 (Parker Laboratories NDC 341-0012-08). The signal is applied across the cathodic hand electrode and the anodic arm electrode.

5.0 Indications for Use

The Bionicare® Stimulator System Model BIO-1000™ is indicated for use as an adjunctive therapy in reducing the level of pain, and stiffness associated with pain, from rheumatoid arthritis of the hand.

6.0 Substantial Equivalence

The Bionicare® Stimulator System, Model BIO-1000™ for rheumatoid arthritis of the hand is substantially equivalent to a legally marketed predicate TENS device. The indications for use and technological characteristics of the Bionicare® Stimulator System, Model BIO-1000™ for rheumatoid arthritis of the hand and the Bionicare® Stimulator System, Model BIO-1000™ for osteoarthritis of the knee, a legally marketed predicate device, are substantially equivalent. The technical characteristics of these devices are described in Table 6.0.1.

Table 6.0.1
Device Comparison Table: Bionicare vs. Predicate Device

	Applicant Device	Predicate Device
Manufacturer	Murray Electronics	Murray Electronics
Device	Bionicare Stimulator	Bionicare Stimulator
Model No.	BIO-1000	BIO-1000
	Rheumatoid Arthritis (Hand)	Osteoarthritis (Knee)
Output Voltage	0-12 volts	0-12 volts
Frequency	100 Hertz	100 Hertz
Pulse Width	.64 ms ¹	.64 ms ¹
Waveform	monophasic spike-pulse	monophasic spike-pulse
Pulse Charge		
Max	20 µC	20 µC
ANSI NS4 ²	Meets Std.	Meets Std.
Channels	single	single
Battery Power	12 v rechargeable	12 v rechargeable
Dimensions	13.2 x 8.5 x 4.5 cm	13.2 x 8.5 x 4.5 cm
Weight (Less Battery)	235 grams	235 grams
Charger	yes	yes

¹ Pulse width fixed, measured at 50% pulse amplitude

² The maximum charge per pulse meets the safety and effectiveness requirements of ANSI/AAMI NS4-1985, Items 3.1-3.1.2.1, 3.2-3.2.5, 4.1-4.2.3.2

Performance Data

The descriptive characteristics presented are precise enough to ensure the substantial equivalence of the Bionicare to a legally marketed predicate device. The descriptive characteristics include the data provided in the device comparison table above, as well as, the findings of performance testing. In particular, the performance data provides greater detail regarding the Bionicare's electrical characteristics, its conformance with voluntary standards, American National Standards Institute Standard for Transcutaneous Electrical Nerve Stimulators ANSI/AAMI NS4-1985, items 3.1-3.1.3, 3.2 - 3.2.5, 4.0 - 4.2.5., Underwriters Laboratories Standard for Medical and Dental Equipment, UL 544 - July 8, 1994, Performance Section 42-Leakage Current, FDA Guide for TENS 510(k) Content, Draft August 1994, Munzner/Hinckley.



Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

JUN - 8 2006

Mr. Kent C. Hoffman
General Manager
Murray Electronics
260 Schilling Circle
Hunt Valley, MD 21031

Re: K983228

Trade Name: Bionicare® Stimulator System, Model BIO-1000™

Regulatory Class: II

Product Code: NYN

Dated: December 15, 1998

Received: December 15, 1998

Dear Mr. Hoffman:

This letter corrects our substantially equivalent letter of March 16, 1999.

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 (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 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 continue 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



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

Enclosure



Protecting and Promoting Public Health

Indications For Use

Device Name

Bionicare® Stimulator System, Model BIO-1000™

Indications For Use

The Bionicare® Stimulator System Model BIO-1000™ is indicated for use as an adjunctive therapy in reducing the level of pain, and stiffness associated with pain, from rheumatoid arthritis of the hand.

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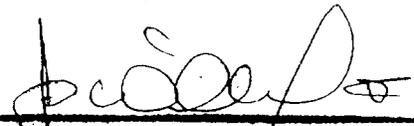
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use:
(Per 21 CFR 801.109)



OR Over-The-Counter:

(Optional Format 1-2-96)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

5
K98322E



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