

JUL 22 1997

510(k) SUMMARY
Bionicare® Stimulator System, Model BIO-1000
April 15, 1997

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in the 510(k), premarket notification was in accordance with 21 CFR § 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 Reason for Submitting the 510(k)

We are submitting this 510(k) to notify FDA of our desire to commercially distribute for the first time the Bionicare® Stimulator System, Model BIO-1000.

4.0 Device Description

The Bionicare® Stimulator, 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 knee and thigh using a standard electrode gel, Spectra 360 (Parker Laboratories NDC 341- 0012- 08). The signal is applied across the cathodic knee electrode and the anodic thigh electrode.

5.0 Indications for Use

The Bionicare Stimulator, Model BIO-1000, is indicated for use in relief of signs and symptoms of osteoarthritis of the knee based on scientific evidence from a multi-center, prospective, parallel, double-blinded, randomized, placebo device controlled clinical study that demonstrated significant improvement in the patient's self evaluation of pain and the physician's global evaluation of the active device treated knee.

6.0 Substantial Equivalence

The Bionicare is substantially equivalent to legally marketed predicate TENS devices. The indications for use and technological characteristics of the Bionicare® Stimulator System, Model BIO-1000 and the three legally marketed predicate devices cited below are substantially equivalent. As summarized in Table A, all the devices are electrical stimulators operating in substantially equivalent output ranges with comparable specifications. Each of the devices is battery powered and has adjustable output amplitudes. The output signals are all monophasic waveforms. The BIO-1000 has a single channel that has a fixed frequency and fixed pulse width in comparison to the predicate single and dual channel stimulators that have variable frequency and variable pulse width. Each device is capable of operating at a frequency of 100 Hertz. The electrical characteristics and the maximum charge of the output pulse of the Bionicare meet the safety and effectiveness requirements of the American National Standards Institute Standard for Transcutaneous Electrical Nerve Stimulators ANSI/AAMI NS4-1985, items 3.1 - 3.1.2.1, 3.2.2 - 3.2.4, 4.2.2 - 4.2.4.

Table A
Technological Characteristics
Bionicare vs. Predicate Devices

	Applicant Device	Predicate Device	Predicate Device	Predicate Device
Manufacturer	Murray Electronics	Verite	Medgeneral	Medgeneral
Device	Bionicare Stimulator	Veri/PPR	Miniceptor	Miniceptor
Model No.	BIO-1000	#800	I	II
Output Voltage	0-12 volts	0-67 volts	0-100 volts	0-90 volts
Frequency	100 Hertz	1-125 Hertz	25-100 Hertz	25-100 Hertz
Pulse Width	.64 ms ¹	.05 - .50 ms ²	.04 - .10 ms ³	.04 - .10 ms ³
Waveform	monophasic spike-pulse	monophasic sloped-pulse	monophasic square-pulse	monophasic square-pulse
Pulse Charge				
Max	20 μ C	NA ⁵	NA	NA
ANSI NS4 ⁴	Meets	NA	NA	NA
Channels	single	dual (single control)	single	dual
Battery Power	12 v rechargeable	67.5 v	rechargeable	rechargeable
Dimensions	13.2 x 8.5 x 4.5 cm	10.8 x 6.4 x 3.2 cm	10.2 x 5.1 x 2.6 cm	10.2 x 5.1 x 2.6 cm
Weight	235 grams	237 grams	176 grams	179 grams
(Less Battery)				
Charger	yes	no	yes	yes

¹ Pulse width fixed, measured at 50% pulse amplitude

² Pulse width variable, range in product literature

³ Pulse width adjustable, range in product literature

⁴ 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

⁵ NA - Not Available from the data found.

The descriptive characteristics presented were precise enough to ensure the substantial equivalence of the Bionicare to legally marketed predicate devices. The descriptive characteristics included the data provided in the device comparison table above, as well as, the findings of performance and clinical testing. In particular, the performance data provides greater detail regarding the Bionicare's electrical characteristics, its conformance with voluntary standards and its safety and efficacy, as reported in a double-blinded, placebo device controlled study.

The findings of this multi-center, prospective, parallel, double-blinded, randomized, placebo device controlled study demonstrate that the Bionicare Stimulator when used daily is safe and effective in the treatment of the signs and symptoms of osteoarthritis of the knee. These findings are summarized below.

Safety

There were no reports of unanticipated adverse effects in this study. As anticipated, skin rash appeared in both the active and placebo device group, 39% and 27% respectively. The rash was transient and completely resolved after stopping or changing the electrode gel. The rash appears to be due to the sustained use of the electrode gel. The observed frequency of skin reactions reported herein appear similar to those reported in the literature for studies of TENS and muscle stimulator devices using comparable gels. Propylene glycol, a common ingredient in approved gels, is a skin irritant that may be in part the cause of these reactions.

Effectiveness

Daily treatment with the Bionicare stimulator resulted in a clinically relevant and statistically significant reduction in the signs and symptoms in the knees of patients affected by osteoarthritis. A repeated measures analysis of the primary clinical outcome data collected in this study demonstrated significant improvements in the Bionicare active device group compared to the placebo device group for the physician's global evaluation of the treated knee and the patient's evaluation of pain in the treated knee. The significant improvements for these clinical outcomes were reported both in terms of the absolute change and their percentage of change. The patient's self evaluation of knee function was not statistically significant, but showed trends favoring the active device group. Secondary efficacy outcome measures showed trends favoring the active device group. In particular, the trends in the measure of morning stiffness, knee tenderness and knee circumference favored the active device group.



JUN - 8 2006

Mr. Kent C. Hoffman
Director, Research and Development
Murray Electronics
260 Schilling Circle
Hunt Valley, MD 21031

K971437
Bionicare Stimulator System Model BIO-1000
Regulatory Class: II
Product Code: NYN
Dated: July 18, 1997
Received: July 21, 1997

Dear Mr. Hoffman:

This letter corrects our substantially equivalent letter of July 22, 1997.

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™

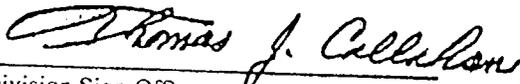
Indications For Use

The Bionicare® Stimulator System Model BIO-1000™ is indicated for use as an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee and for overall improvement of the knee as assessed by the physician's global evaluation (see clinical studies).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use:
(Per 21 CFR 801.109)

(Optional Format 1-2-96)


(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K971437