NOV 1 2 2003

K031820 1/2

Multinational

1223 Wilshire Boulevard, Suite 112
Santa Monica, California 90403
Tel/Fax (310) 393-1749

510(k) SUMMARY

Submitter's name:	Multinational
Address:	1223 Wilshire Blvd, Ste. 112
Phone:	310-393-1749
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Name of contact person:	Grace Holland Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411 fax: 949-552-2821 grace@regulatoryspecialists.com
Date the summary was prepared:	November 4, 2003
Name of the device:	Besmed 550 and Besmed 660
Trade or proprietary name:	Besmed 550 and Besmed 660
Common or usual name:	Electrical muscle stimulation device
Classification name:	Power muscle stimulator (per 21 CFR section 890.5850)

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

BioStim Digital NMS, manufactured by BioMedical Life Systems. The clearance number is K010749.

Description of the device:

BE-550 is a single-channel battery operated muscle stimulation system. It comprises two main components, namely, an electronic stimulatory module which generates the required stimulation signals, and skin electrodes with lead wires.

The product is supplied with a set of single sided adhesive electrodes, an instruction manual, and a set of batteries. Power is derived from three AA cells located in a compartment protected by a removable battery cover.

The BE-550 is intended to be used as an electronic muscle stimulator.

BE-660: Is the same as the BE-550 model, but is a two-channel battery operated muscle stimulation system.

Intended use of the device:

Electrically powered devices intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area.

Indications For Use include:

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

Summary of the technological characteristics of our device compared to the predicate device:

As can be seen in both the Comparison and Standards sections, the Besmed devices and the BioStim device have similar technological characteristics and are equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 2003

Multinational
C/o Ms. Grace Holland
Regulatory Specialists, Inc.
3722 Ave. Sausalito
Irvine, CA 92606

Re: K031820
Trade Name: BE-550 and BE-660
Regulation Numbers: 21 CFR 890.5850
Regulation Names: Powered muscle stimulator
Regulatory Class: II
Product Codes: IPF
Dated: September 8, 2003
Received: September 10, 2003

Dear Ms. Holland:

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,

Miriam C. Provost

for 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

Indications For Use Statement

510(k) Number (if known):_____

Device Name: BE-550 and BE-660

Indications For Use:

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Indications For Use include:

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(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K031820