K033174

JUN 3 0 2004

510(k) SUMMARY
(As required by 21 CFR 807.93)

(1) GENERAL

Submitter Name:	BioMedical Life Systems, Inc.
Address:	P.O. Box 1360 Vista, CA 92085
Phone:	760-727-5600
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Contact:	Richard Saxon
Date Prepared:	26 September 2003

(2) DEVICE

Name:	
Trade or Proprietary Name:	BMLS03-3
Common or Usual Name:	Neuromuscular Stimulator
Classification Name:	21 CFR 890.5850 Powered Muscle Stimulator, Class II
Product Code:	IPF

(3) PREDICATE DEVICES

Trade or Proprietary Name:	BMLS02-5
Common or Usual Name:	Neuromuscular Stimulator
Classification Name:	21 CFR 890.5850 Powered Muscle Stimulator, Class II
Product Code:	IPF
Trade or Proprietary Name:	BMLS03-1
Common or Usual Name:	Neuromuscular Stimulator
Classification Name:	21 CFR 890.5850 Powered Muscle Stimulator, Class II
Product Code:	IPF

(4) DEVICE DESCRIPTION

The BMLS03-3 is a portable, battery-powered four channel neuromuscular stimulator. The output waveform can be set to symmetrical or asymmetrical biphasic rectangular. The pulse rate range is 1-120 Hz. The pulse width range is 50-400 microseconds. The output intensity range is 0-100 milliamps. It can be set to constant, cycled, or reciprocating modes, and has several pre-programmed modes. All device functions and status are displayed on a graphic LCD.

(5) INTENDED USE

The BMLS03-3 is recommended for use for the following conditions:

- Prevention or retardation of muscle disuse atrophy;
- Relaxation of muscle spasm;
- Muscle reeducation;
- Maintaining and increasing the range of motion;
- Increasing local blood circulation
- Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis.

(6) COMPARISON TO PREDICATE DEVICE

Non-clinical Testing:	The BMLS03-3 is identical to the predicate (BioMedical Life Systems, Inc.) BMLS02-5 device in every way except for output pulse strength. The output pulse strength of the BMLS03-3 is equivalent to the predicate (BioMedical Life Systems, Inc.) BMLS03-1. This equivalency was determined through bench testing.
Clinical Testing:	Not applicable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 0 2004

Mr. Gary Busset
BioMedical Life Systems, Inc.
P.O. Box 1360
Vista, California 92085-1360

Re: K033174
Trade/Device Name: Model BMLS03-3
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: IPF
Dated: June 4, 2004
Received: June 7, 2004

Dear Mr. Busset:

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

510(k) Number (if known): K033174

Device Name: (EMS) Electrical Neuromuscular Stimulator
For Muscle Reeducation - Class II
Model BMLS03-3

Indications for Use: External electrical neuromuscular stimulation using biphasic output is indicated as therapeutic adjunct for: prevention or retardation of muscle disuse atrophy; relaxation of muscle spasm; muscle reeducation; maintaining and increasing the range of motion; increasing local blood circulation and as immediate postsurgical stimulation of calf muscles to prevent venous thrombosis.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21CFR807 Subpart C)

(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 K033174