



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 23 2004

Mr. Gary Bussett
Biomedical Life Systems, Inc.
2448 Cades Way
P.O. Box 1360
Vista, California 92085

Re: K041388

Trade/Device Name: Combination Electrical Neuromuscular Stimulator, Interferential Stimulator, and Transcutaneous Electrical Nerve Stimulator (TENS), Model BML S04-1

Regulation Numbers: 21 CFR 890.5850, 882.5890

Regulation Names: Powered muscle stimulator, Transcutaneous electrical nerve stimulator for pain, and inferential current stimulator.

Regulatory Class: II

Product Code: GZJ, IPF, LIH

Dated: November 12, 2004

Received: November 15, 2004

Dear Mr. Bussett:

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

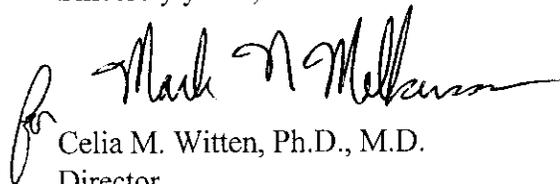
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comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 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 (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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "W".

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 : K041388

Device Name: Combination Electrical Neuromuscular Stimulator, Interferential Stimulator, and Transcutaneous Electrical Nerve Stimulator (TENS), Model BMLS04-1

Indications for Use:

Muscle Stimulator Mode:

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.

Interferential Mode:

Interferential Stimulation is used for symptomatic relief and management of chronic pain and/or as an adjunctive treatment in the management of postsurgical and post-traumatic acute pain.

TENS Mode:

Transcutaneous Electrical Nerve Stimulation (TENS) is used for symptomatic relief and management of chronic pain and/or as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21CFR807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Millerson
(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

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