Section 5: 510(k) Summary: K100862

The following information is provided as required by 21 CFR § 807.87 for the Bodyflow®-P2CH 510(k) premarket notification for and in accordance with FDA's *"Guidance Document for Powered Muscle Stimulator 510(k)s", June 9, 1999.*

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the Bodyflow P2CH is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices.

Applicant:	Physiomed Elektromedizin AG Hutweide 10 D-91220 Schnaittach / Laipersdorf Phone: +49 9126 – 25 87 - 17 Facsimile: +49 9126 - 25 87-717 Registration Number: 3002892330
Date of submission:	March 8, 2010
Proprietary Name:	Bodyflow®-P2CH
Common Name:	Powered Muscle Stimulator
Classification Status:	21 CFR 890.5850
Product Code:	IPF
Panel:	Physical Medicine
Predicate Device:	Physiomed's LymphaVision, K003896, is substantially equivalent, for the purpose of this 510(k), to other devices that have received 510(k) clearance for similar indications for use.

Device Description: The Bodyflow®-P2CH is a device which delivers muscle stimulation by applying an electrical current to electrodes, which are attached on the patient's skin. The output and waveform is adjustable according to the intended treatment of patient. The stimulator has 2 output channels, accessed through jacks at the top of the housing, so that it may stimulate either 2 or 4 patient electrodes. The device is powered by permanently installed, rechargeable batteries.

Intended Use: As prescribed by a physician for the following:

- Increased local blood circulation
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

Discussion of performance testing: Based on the output measurements, calculations, and safety testing/inspection; the Bodyflow®-P2CH is safe with respect to electrical leakage current, electrode and lead wire safety, as well as output current and power density. Testing performed in accordance with the accepted FDA requirements of IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety, IEC 60601-1-2, Medical Electrical Equipment, Part 1: General Requirements for Safety. Collateral Standard: Electromagnetic Compatibility-Requirements and Test and IEC 60601-2-10, Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators, found the Bodyflow®-P2CH passed all of the applicable test.

Technological Characteristics and Substantial Equivalence

Output specifications, device design, waveforms and programmability demonstrated the Bodyflow®-P2CH to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Birgit Schmid
Physiomed Elektromedizin AG
Hutweide 10
D-91220 Schnaittach / Laipersdorf
Germany

APR 21 2011

Re: K100862
Trade/Device Name: Bodyflow-P2CH
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: II
Product Code: IPF
Dated: April 12, 2011
Received: April 14, 2011

Dear Ms. Schmid:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

Indications for Use

510(k) Number: K100862

Device Name: Bodyflow®-P2CH

Indications For Use: The Bodyflow®-P2CH is a powered muscle stimulator intended for

- Increased local blood circulation
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100862

Page 1 of 1