APR 2 6 2013

Section 5: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for the BODYTRONIC 200 510(k) premarket notification.

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 BODYTRONIC 200 is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate device.

Applicant:	Bauerfeind AG Triebeser Strasse 16 D-07937 Zeulenroda-Triebes Phone: +49 36628 661350 Facsimile: +49 36628 663153 Registration Number: 8010507
Date of Preparation:	December 20, 2012
Proprietary Name:	BODYTRONIC 200
Common Name:	Plethysmograph, Photoelectric
Classification Status:	21 CFR 870.2780
Product Code:	JOM
Panel:	Cardiovascular

Predicate Device
Bauerfeind's BODYTRONIC 200 is substantially equivalent, for the purpose of this 510(k), to Elcat vasoquant VQ1000 D-PPG (K944395).

Device Description
The BODYTRONIC 200 is based on light reflection rheography. A small quantity of infrared light is radiated into the legs just above the ankles, and the reflected light is measured. On the basis of the quantity of reflected light over a defined period, conclusions can be drawn about the flow of blood in the veins.

Intended Use
The BODYTRONIC 200 is a photoelectric plethysmograph intended for the measurement of the leg vein function.

Technological Characteristics and Substantial Equivalence
The BODYTRONIC 200 in accordance to the following international standards:

- IEC 60601-1 – Electrical Safety
- IEC 60601-1-1 – Medical Electrical Systems
- IEC 60601-1-2 – Electromagnetic Compatibility
- IEC 60601-1-6 – Usability
- IEC 62304 – Software Life-Cycle
- ISO 14971 – Risk Management
- ISO 10993-1 – Biocompatibility
- IEC 62471 – Photobiological safety of lamps and lamp systems
- IEC 62133 – Safety requirements for portable sealed secondary cells
- IEC 60950-1 – Information technology equipment

The BODYTRONIC 200 is substantially equivalent to its predicates because it has the same intended use and similar technological characteristics.

Both the BODYTRONIC 200 and its predicates are intended for the measurement of the leg vein function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

April 26, 2013

Bauerfeind Ag
Ines Exner
Triebeser Strasse 16
Zeulenroda-triebes, 07937 GM

Re: K123921
Trade/Device Name: Bodytronic 200
Regulation Number: 21 CFR 870.2780
Regulation Name: Plethysmograph, Photoelectric
Regulatory Class: Class II
Product Code: JOM
Dated: January 21, 2013
Received: February 20, 2013

Dear Ines Exner:

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.htmfor 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,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Section 4: Indication for Use Statement

Indications for Use

510(k) Number (if known): not yet assigned

Device Name: BODYTRONIC 200

Indications for Use: The BODYTRONIC 200 is a photoelectric plethysmograph intended for the measurement of the leg vein function.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

Owen P. Faris -S
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