FEB -7 2011

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number : K082254

A. Submitter:

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Contact: I J Meeuwsen

Date Prepared: January 24, 2011

B. Device Names:

Classification name	Body Composition Analyzer
Common/usual name	Body Composition Analyzer
Proprietary name	Bodystat 1500MDD Body Composition Monitoring Unit

C. Predicate Device:

The BODYSTAT®1500MDD Body Composition Monitoring Unit is substantially equivalent to the following previously cleared and legally marketed devices:

- K994242, Bodystat 1500MDD Body Composition Monitoring Unit.
- K002835, Bodystat Quadscan Quad Frequency Monitoring Unit

D. Device Description:

The Bodystat 1500MDD Body Composition Monitoring Unit is a light weight, handheld, battery-operated device that uses bio-electrical impedance analysis (BIA) to measure the impedance of the flow of an electrical current through the body. The impedance of tissue is proportional to the amount of fluid in the tissue; water is low in fat tissues, thus fat tissue has a high impedance, and high in lean tissues, thus lean tissue has a low impedance. The subject's age, sex, height, weight, waist measurement, and hip measurement are also used to calculate various values.

In practice, a small constant current is passed between electrodes spanning the body and the voltage drop between electrodes provides a measure of impedance. Prediction equations, previously generated by correlating impedance measures against an independent estimate of TBW (total body water), may be used subsequently to convert a measured impedance to a corresponding estimate of TBW. Lean body mass is then calculated from this estimate using an assumed hydration fraction for lean tissue; Bodystat uses a proprietary regression equation for this calculation. Fat mass is

calculated as the difference between body weight and lean body mass. A body composition analysis report is comprised of Body Fat, Lean Body Mass, Dry Lean Mass, Total Body Water, and Optimal Ranges. Metabolic rates, Waist/Hip Ratio, and BMI are also reported. In addition, raw values are shown for Impedance at 5 kHz and at 50 kHz. The Bodystat 1500MDD contains separate equations for children aged 6 – 17 years and for adults aged 18 – 70 years.

E. Intended Use:

For the purposes of performing a non-invasive BIA measurement on normal healthy human adults and children to determine their Body Composition status.

These measurements include Body Mass Index (BMI), waist/hip ratio, tissue impedance. These measurements are used to calculate the estimated levels of body fat, body lean and dry lean, total body water, and metabolic rates.

Bodystat BODY MANAGER and WELLNESS SOFTWARE PROGRAMS are automatically included with this device.

The **Body Manager Program** is designed for when a client returns to be tested in order to track their changes in body composition over a period of time.

The **Wellness Program** is designed for first time assessments on subjects. The program's graphical presentations provide information on each of the specific measurements in an educational format.

F. Comparison with the Predicate Device:

The BODYSTAT®1500MDD Body Composition Monitoring Unit is a hardware and software modification of the previously cleared Bodystat 1500MDD device, and measures at the additional frequency of 5 kHz like the Quadscan device.

Based on the data and information presented here, the BODYSTAT®1500MDD Body Composition Monitoring Unit is substantially equivalent to the previously cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. I. J. Meeuwsen
President
Bodystat® Ltd.
P.O. Box 50
Douglas, Isle of Man, IM99 1DQ
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FEB - 7 2011

Re: K082254
Trade/Device Name: BODYSTAT □ 1500MDD Body Composition Monitoring Unit
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: September 27, 2010
Received: September 30, 2010

Dear Mr. Meeuwsen:

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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number : K082254

Device Name: **BODYSTAT□1500MDD Body Composition Monitoring Unit**

Indications for Use:

For the purposes of performing a non-invasive BIA measurement on normal healthy human adults and children to determine their Body Composition status.

The measurements include Body Mass Index (BMI), waist/hip ratio, tissue impedance at 5kHz and at 50kHz. These measurements are used to calculate the estimated levels of body fat, body lean and dry lean, total body water, and metabolic rates.

Bodystat BODY MANAGER and WELLNESS SOFTWARE PROGRAMS are automatically included with this device.

The **Body Manager Program** is designed for when a client returns to be tested in order to track their changes in body composition over a period of time.

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Prescription Use ___ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _X____ (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 Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K082254