MAR 2 0 2009

510(k) Summary

IntelaMetrix, Incorporated – BodyMetrix BX2000™

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92(c).

Owner's Name and Address:

IntelaMetrix, Inc.
6246 Preston Avenue
Livermore, CA 94551
(925) 606-7044 – Telephone
(925) 371-3903 – Fax

Contact Information:

Heidi Stark
IntelaMetrix, Inc.
6246 Preston Avenue
Livermore, CA 94551
(925) 606-7044 – Telephone
(925) 371-3903 – Fax

Date Prepared:

March 9, 2009

Device Trade Name:

BodyMetrix BX2000™

Common Name:

Ultrasound Body Composition Device

Classification Name:

Class II – Analyzer, Body Composition, Ultrasonic
(21 CFR 870.2770)

Predicate Devices:

K810116
Isorobic Skinfold Caliper

Teratech Corporation
TERASON T2000 Ultrasound System
K051334

Description of the Device:

BodyMetrix BX2000™ is a portable, hand-held device that uses A-mode ultrasound to measure tissue thickness. The device is powered and communicates with a portable or desktop computer through a USB interface. A piezoelectric transducer is used to generate and transmit ultrasound sound waves into tissue. The reflected sound waves are detected by a second and separate

piezoelectric transducer and digitized before the data is transferred through a USB cable to the computer.

Indications for Use:

(1) BodyMetrix BX2000 is indicated for the measurement of localized fat layer thickness and localized muscle thickness. When used with the BodyView Software it can be used to estimate total body fat percentage (%BF). The BX2000 is only intended to be used on generally healthy adults and children (6 or older) and is not for diagnosis of disease or condition.

(2) The BodyView Software is indicated for the calculation of the estimated total body fat percentage (%BF), localized fat layer thickness, and localized muscle thickness. The BodyView Software is indicated for calculating Waist-to-Hip Ratio (WHR), and Body Mass Index (BMI). The BodyView Software is indicated for estimating Basal Metabolic Rate (BMR). The BodyView software can track changes in the measurements, and generate body composition reports.

Performance Data:

Preclinical Testing

BX-2000 acoustic output limits are:

ISPPA.3	60 mW/cm^2	(Maximum)
ISPTA.3	0.02 mW/cm^2	(Maximum)
MI	0.02	(Maximum)

Clinical Testing

Clinical testing was conducted and submitted as part of the 510(k) application to confirm that BodyMetrix BX2000™ is as safe and effective device for measuring tissue thickness and estimating percentage body fat.

Substantial Equivalence:

BodyMetrix BX2000 and its predicate devices are all devices that use low frequency, ultrasound, and are safe for this application. The BodyMetrix BX2000™ uses the same measurement points and formulas that are used for skinfold calipers. The differences in the technological characteristics of BodyMetrix BX2000 and its predicate devices do not raise any new issues of safety or efficacy. Thus, the BodyMetrix BX2000 is substantially equivalent to the predicate device for measurement of human tissue thickness.

Conclusion:

Based on the indications for use, technological characteristics, performance testing and comparison to predicate devices, the proposed device has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2009

Ms. Heidi Stark
VP and CFO
IntelaMetrix®
6246 Preston Avenue
LIVERMORE CA 94551

Re: K082147
Trade/Device Name: BodyMetrix BX 2000
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: OMV
Dated: March 9, 2009
Received: March 10, 2009

Dear Ms. Stark:

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 os 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 one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K082147**

Device Name: – **BodyMetrix BX 2000**

Indications For Use:

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Prescription Use _____ AND/OR Over-The-Counter Use __X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 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, Abdominal,
and Radiological Devices
510(k) Number K082147