K052319
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APR 4 2006

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510 (k) Summary
ImpediMed Imp SFB7 Body Composition Analyzer

APPLICANT INFORMATION

Company Name and address:	ImpediMed Limited 4B/2404, Logan Road Eight Mile Plains Brisbane, QLD – 4113
Contact Name and numbers:	Mr Neville Bertwistle VP Operations Phone: (+61) 7 3423 1777 Fax: (+61) 7 3423 1496 E-mail: nbertwistle@impedimed.com
Date of summary prepared:	January 27, 2006

DEVICE IDENTIFICATION

Trade/Proprietary name:	Imp SFB7 Body Composition Analyzer
Classification name:	Impedance Plethysmograph
Regulation number/CFR section:	21 CFR 870.2770
Product code:	DSB
Classification panel:	Cardiovascular
Device class:	Class II

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PREDICATED DEVICE

Company:	Xitron Technologies, Inc
Device name:	Bio-Impedance Analyzer
510 (K) number:	K 904109
Product code:	DSB
Classification panel:	Cardiovascular
Device class:	Class II

INDICATIONS FOR USE

The indications for use of this device are healthy patients, who wish to have their body composition estimated, in the home and clinical environment.

DEVICE DESCRIPTION

The Imp SFB7 is a multiple frequency bioelectrical impedance analyzer. The device accurately measures current, voltage and phase angle, and calculates impedance, resistance and reactance. These measurements and calculations are used to estimate the body composition: fat-free mass (FFM) and fat mass (FM), and fluid distribution: total body water (TBW), intracellular fluid (ICF), and extracellular fluid (ECF).

The device has 2 modes of operation

1. MFBIA Mode – This is a Multiple Frequency Bioelectrical Impedance mode. Impedance readings are taken by applying all 256 frequencies sequentially in a very short time in the range of 4 kHz to 1000 kHz.

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2. Selected Frequencies Mode – Any three user selected frequencies between 4 kHz to 1000 kHz and five pre set (5, 10, 50, 100, 500 kHz) frequencies are used to measure impedance of a subject.

In MFBIA and Selected Frequencies mode, selection of single, continuous measurements or measurements at a selected interval of time is available. Over 1000 records can be stored and analyzed on Imp SFB7 or can be downloaded to a PC or laptop loaded with an optional BioImp Body Composition Analysis software via an Ethernet connection.

TECHNOLOGICAL CHARECTERISTICS

The ImpediMed Imp SFB7 Body Composition Analyzer is a rechargeable battery powered, accurate, portable, multiple frequency bioelectrical impedance analysis instrument operating in tetra-polar (4 leads – 2 current source and 2 voltage sensing) mode. The device accurately measures current, voltage and phase angle, and calculates impedance, resistance and reactance.

Bioimpedance analyzers calculate complex impedance or opposition to the flow of an electric current by the body. The applied electrical current travels through the extra cellular fluid of the body and through the lean muscle-organs via the intracellular fluid. Impedance is low in lean tissue, extra cellular fluid and intracellular fluid, where electrolytes are primarily contained, but high in fat tissue because fat is primarily an insulator containing very few conducting elements. Therefore impedance can be related to the total water volume of the body because the impedance is a direct measure of both intracellular and extra cellular fluid. In the Imp SFB7 a small constant current, typically 200 uA RMS, with in the frequency range of 4 kHz to 1000 kHz sequentially, is passed between two current electrodes spanning the body. The voltage drop measured between a second pair of voltage-sensing electrodes is used to calculate the

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complex impedance value. The calibration of the device may be checked with the aid of the supplied test cell.

MFBIA Mode:

Imp SFB7 in MFBIA mode works by calculating the complex impedance, applying all 256 frequencies (4 kHz to 1000 kHz) sequentially in a very short time to reduce the time to complete the test and the inconvenience to the subject.

Impedance calculations made over a range of frequencies (4 kHz-1000 kHz) are used to create a Cole-Cole plot. Hanai modeling, which treats body as a concentrated suspension of cells in a conductive medium is used to estimate extracellular fluid (ECF) at low frequency and total body water (TBW) at high frequency. Intra cellular fluid (ICF) is then estimated by the difference between TBW and ECF. Fat free mass (FFM) is estimated from measured TBW assuming the hydration constant of a person as 73.2%. Fat mass (FM) is estimated from the difference between body mass and fat free mass.

Selected Frequencies Mode:

Imp SFB7 in Selected Frequencies mode has 5 pre set frequencies (5, 10, 50, 100, 500 kHz) and allows user to enter 3 frequencies of their choice in the range of 4 kHz to 1000 kHz to measure impedance of a subject. It measures, displays, and stores the impedance readings for these selected frequencies.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 4 2006

Mr. Neville Bertwistle
VP Operations
ImpediMed Pty Limited
Building 4B/2404 Logan Road,
Eight Mile Plains
Brisbane, Queensland
AUSTRALIA 4113

Re: K052319
Trade/Device Name: ImpediMed Imp SFB7 Body Composition Analyzer & BioImp Body Composition Analyzer PC Software
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: undated
Received: March 13, 2006

Dear Mr. Bertwistle:

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

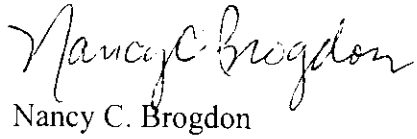
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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 the labeling regulation, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 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,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): **K052319**

Device Name(s): Imp SFB7
BioImp Body Composition Analyzer PC Software

Indications for Use:

(1) Imp SFB7 – A bioelectrical impedance analyzer/monitor that is intended to estimate the following body composition parameters: Fat-free Mass (FFM), Fat Mass (FM), Total Body Water (TBW), Intra cellular Fluid (ICF), Extra cellular Fluid (ECF), and Body Mass Index (BMI). The device measures current, voltage and phase angle (Phi), and from these values calculates resistance (R), reactance (Xc), and impedance (Z), which are used to estimate the above body composition parameters. The device/software will also display the Cole-Cole plot, resistance vs. frequency plot, reactance vs. frequency plot, subject height, weight, age and sex.

(2) BioImp Body Composition Analyzer PC Software: A PC software package that is intended to be used only with the ImpediMed Imp SFB7 Analyzer for uploading the MFBIA mode data on to the PC from Imp SFB7 via an Ethernet port for storing, processing and analysing of MFBIA bioimpedance measurements. This displays Cole-Cole plot, body composition parameters: Fat-free Mass (FFM), Fat Mass (FM), Total Body Water (TBW), Intra cellular Fluid (ICF), Extra cellular Fluid (ECF), Body Mass Index (BMI), and subject height, weight, age, sex, time, and date of measurement, Practitioner's name and Device serial number, and bioelectrical parameters resistance (R), reactance (Xc), and impedance (Z) and phase angle (Phi) at different frequencies (Between 4 kHz to 1000 kHz). The software can be used to generate patient body composition report displaying all the parameters stated above.

These devices are intended to be used only on healthy patients, who wish to have their body composition estimated in the home or clinical environment.

Prescription Use _____ AND/OR Over-The-Counter Use ___✓___
(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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052319

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