K050395
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JUL 13 2005

ImpediMed Limited

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510 (k) Summary
ImpediMed Imp DF50 Body Composition Analysis

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 General Manager Phone: (+61) 7 3423 1777 Fax: (+61) 7 3423 1496 E-mail: nbertwistle@impedimed.com
Date of summary prepared:	Dec 24, 2004

DEVICE IDENTIFICATION

Trade/Proprietary name:	Imp DF50 Body Composition Analysis
Classification name:	Impedance Plethysmograph
Regulation number/CFR section:	21 CFR 870.2770
Product code:	~~DSB~~ MNW
Classification panel:	Cardiovascular
Device class:	Class II

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1.

Company:	RJL Systems, Inc
Device name:	BIOELECTRICAL IMPEDANCE ANALYZER #101
510 (K) number:	K 830292
Product code:	DSB

2.

Company	BODYSTAT LTD
Device name:	BODYSTAT 1500MDD BODY COMPOSITION MONITORING UNIT
510 (K) number:	K 994242
Product code:	MNW

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INTENDED USE / INDICATIONS FOR USE

Body Composition Analysis, i.e. 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 water (ICW), and extracellular water (ECW).

DEVICE DESCRIPTION

The Imp DF50 is a single frequency bioelectrical impedance analyser. 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, intracellular water, and extracellular water.

TECHNOLOGICAL CHARECTERISTICS

The ImpediMed Imp DF50 Body Composition Analyzer is a battery powered, accurate, hand-held, single frequency, bioelectrical impedance analysis instrument operating in tetra-polar mode. The device accurately measures current, voltage and phase angle, and calculates impedance, resistance and reactance.

Bioelectrical impedance analysis measures the impedance or opposition to the flow of an electric current through the body fluids contained mainly in the lean and fat tissue. Impedance is low in lean tissue, where intracellular fluid and electrolytes are primarily contained, but high in fat tissue. Impedance is thus related to total body water volume. In practice, a small constant current, typically 200 uA± 10uA peak-to-peak at a fixed frequency of 50 kHz± 100Hz is passed between two current electrodes spanning the body. The voltage

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drop measured between a second pair of voltage-sensing electrodes provides a measure of impedance. The performance of the device may be checked with the aid of a calibration circuit (supplied as an accessory) for quality assurance or servicing purposes.

Prediction equations from peer reviewed journal articles, generated by correlating impedance measures against an independent estimate of Total Body Water (TBW), may be used to convert 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. Fat mass is subsequently calculated as the difference between body weight and lean body mass.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2005

Mr. Neville Bertwistle
VP Operations
ImpediMed Limited
Building 4B, Garden City Office Park
P.O. Box 4612
Eight Mile Plains QLD 4113
AUSTRALIA

Re: K050395
Trade/Device Name: Imp DF50 and Body Composition Analysis software
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: June 24, 2005
Received: June 24, 2005

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 (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). 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 (21 CFR Part 807); 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/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
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): K050395

Device Name: Imp DF50 and Body Composition Analysis software

Indications For Use:

A body composition analyzer and a software package that will estimate display and store the following body composition parameters:

Fat-free Mass (FFM), Fat Mass (FM), Total Body Water (TBW), Intra cellular Water (ICW), Extra cellular Water (ECW), Body Mass Index (BMI) and Basal Metabolic Rate (BMR). 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 user's height, weight, age, % ideal weight, time and date of measurement, Practitioner's name and Device serial number.

This device is intended for use on healthy children (9 - 16 years old), general and obese adult subjects, only for body composition assessment in the home or clinical environment.

Prescription Use _____ AND/OR Over-The-Counter Use _YES_
(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 K050395