ImpediMed Ltd

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510 (k) Summary
ImpediMed Imp XCA ExtraCellular Fluid Analysis

APPLICANT INFORMATION

Company Name and address:	ImpediMed Ltd 4B/2404, Logan Road Eight Mile Plains Brisbane, QLD – 4113
Contact Name and numbers:	Mr Roger Render VP Quality & Regulatory Phone: (+61) 7 3423 1777 Fax: (+61) 7 3423 1496 E-mail: rrender@impedimed.com
Date of summary prepared:	March 27 2007

DEVICE IDENTIFICATION

Trade/Proprietary name:	Imp XCA ExtraCellular Fluid Analysis
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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1.

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

2.

Company	Bodystat Ltd
Device name:	Bodystat Quad Scan 4000
510 (K) number:	K 002835
Product code:	MNW
Classification panel:	Cardiovascular
Device class:	Class II

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INTENDED USE / INDICATIONS FOR USE

The Imp XCA: A bioelectrical impedance analyzer/monitor utilizing impedance ratios that supports the measurement of extra cellular fluid volume differences between the arms to aid in the clinical assessment of unilateral lymphoedema of the arm. This device is not intended to diagnose or predict lymphoedema of an extremity.

Lymphoedema Analysis PC Software - an optional PC software package that is intended to be used only with the ImpediMed Imp XCA analyzer/monitor for uploading the data on to the PC from the Imp XCA via an infrared transfer for storing, processing and analyzing of bioimpedance measurements.

DEVICE DESCRIPTION

The Imp XCA 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 extracellular fluid (ECF) allowing for the clinical assessment of unilateral Lymphedema of the arm.

TECHNOLOGICAL CHARECTERISTICS

The ImpediMed Imp XCA ExtraCellular Fluid 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 fluid volume. The tissue and organs of the body are composed of cells surrounded by a cell membrane. This membrane separates fluid inside

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cells called intracellular fluid (ICF) from that surrounding the cells termed as extracellular fluid (ECF) that act as conductors to the flow of current through the body.

However, the cell membrane and tissue interfaces because they are 'imperfect capacitors' act as a barrier to penetration of current at low frequencies. Thus the total impedance and phase angle of alternating current flow will be frequency dependent.

Therefore, an alternating electric current has two possible pathways through a biological tissue; at low frequencies it will pass only through the extracellular fluid since the capacitance of the cell membrane acts as a barrier to penetration by the current, while at high frequencies the current will cross the cell membrane and take a path through both the ICF and ECF, i.e. the total fluid volume.

The ImpediMed Imp XCA is specifically designed for segmental bioelectrical impedance analysis to measure the ECF of the arms in which a small constant current, typically 200 uA± 10uA peak-to-peak at a fixed low frequency of 10 kHz is passed between two current electrodes spanning the body. The voltage 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.

Bioelectrical impedance basics, simple mathematics, bioelectrical and anthropometric parameters from peer reviewed published journal articles are used to convert measured impedance to a corresponding estimate of extracellular fluid ratio (extracellular fluid index or lymphoedema index), and extracellular fluid volume difference between the arms. These

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estimates can be used as alternatives to the current circumferential measurements and water immersion methods, to indicate trends and to assist in the assessment of the development of Lymphedema.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Roger Render
VP Quality Regulatory
ImpediMed Limited
4B / 2404 Logan Road
Brisbane
Queensland 4113
AUSTRALIA

MAR 30 2007

Re: K050415
Trade/Device Name: Imp XCA with Lymphoedema Analysis PC Software
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: OBH
Dated: Undated
Received: March 29, 2007

Dear Mr. Render:

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) 276-3150. 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 Statement

Device Name: Imp XCA with Lymphoedema Analysis PC Software

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(2) Lymphoedema Analysis PC Software – an optional PC software package that is intended to be used only with the ImpediMed Imp XCA analyzer/monitor for uploading the data on to the PC from the Imp XCA via an infrared transfer for storing, processing and analyzing of bioimpedance measurements.

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 K050145