OCT - 3 2008

ImpediMed Limited

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510 (k) Summary
ImpediMed L-Dex U400 BIS Extra Cellular Fluid Analysis

APPLICANT INFORMATION

Company Name and address: ImpediMed Limited
Unit1
50 Parker Court
Pinkenba, QLD – 4008

Contact Name and numbers: Mr Phillip Auckland
Chief Operations Officer
Phone: (+61) 7 3860 3700
Fax: (+61) 7 3260 1225
E-mail: pauckland@impedimed.com

Date of summary prepared: August 26, 2008

DEVICE IDENTIFICATION

Trade/Proprietary name:	L-Dex U400 BIS Extra Cellular 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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PREDICATED DEVICE

Company:	ImpediMed Limited
Device name:	Imp XCA Extra Cellular Fluid Analysis
510 (K) number:	K050415
Product code:	DSB
Classification panel:	Cardiovascular
Device class:	Class II

PREDICATED DEVICE

Company:	ImpediMed Limited
Device name:	Imp SFB7 Body Composition Analyzer
510 (K) number:	K052319
Product code:	DSB
Classification panel:	Cardiovascular
Device class:	Class II

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INTENDED USE / INDICATIONS FOR USE

The L-Dex U400: 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 lymphedema of the arm in women. This device is not intended to diagnose or predict lymphedema of an extremity.

Lymphedema Analysis PC Software – an optional PC software package that is intended to be used only with the ImpediMed L-Dex U400 analyzer/monitor for uploading data on to the PC from the L-Dex U400, processing and analyzing of bioimpedance measurements.

DEVICE DESCRIPTION

The L-Dex U400 is a multi frequency bioelectrical impedance analyser. The device accurately measures current, voltage and phase angle, and calculates impedance, resistance and reactance as with the XCA. These measurements and calculations are used to estimate extra cellular fluid (ECF) allowing for the assessment of the development of unilateral Lymphedema of the arms.

TECHNOLOGICAL CHARECTERISTICS

The ImpediMed L-Dex U400 Extra Cellular Fluid Analyzer, like the SFB7, is a battery powered, accurate, multi 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 cells called intracellular

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fluid (ICF) from that surrounding the cells termed as extra cellular 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.
The ImpediMed L-Dex U400 is specifically designed for segmental bioelectrical impedance analysis to measure the ECF of the arms in which a small alternating constant current of 200uA RMS at a frequency of 4kHz± 100Hz to 1000 kHz± 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 impedance value. The performance of the device may be checked with the aid of a calibration circuit (supplies 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 extra cellular fluid ratio (extra cellular fluid index or lymphedema index - referred to as L-Dex), and differences between the arms. These estimates can be used as alternatives to the current circumferential measurements and water immersion methods, to indicate trends toward the potential development of Lymphedema.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 2008

Mr. Phillip Auckland
Chief Operations Officer
ImpediMed Limited
Unit 1, 50 Parker Court
Pinkenba Queensland 4008
AUSTRALIA

Re: K080825
Trade/Device Name: ImpediMed L-Dex U400 and optional Lymphedema Analysis PC Software
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: OBH
Dated: August 26, 2008
Received: August 29, 2008

Dear Mr. Auckland:

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.

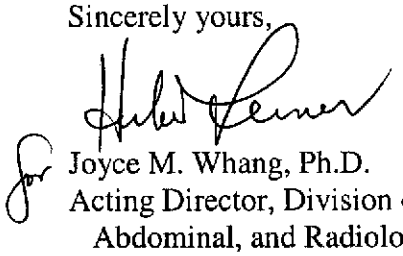
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh.dsma/dsmamain.html.

Sincerely yours,



for Joyce M. Whang, Ph.D.
Acting 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): **K080825**

Device Name: **ImpediMed L-Dex U400**

Indications for Use:

The L-Dex U400: 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 lymphedema of the arm in women. This device is not intended to diagnose or predict lymphedema of an extremity.

Lymphedema Analysis PC Software – an optional PC software package that is intended to be used only with the ImpediMed L-Dex U400 analyzer/monitor for uploading data on to the PC from the L-Dex U400, processing and analyzing of bioimpedance measurements.

Prescription Use _✓_ **(Part 21 CFR 801 Subpart D)** **AND/OR** **Over-The-Counter Use** _____ **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K080825

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