# L-Dex® U400
# ExtraCellular Fluid Analyzer

## 510(k) Traditional
## Premarket Notification
## Summary

| | |
|---|---|
| **Device Trade or Proprietary Name:** | **L-Dex® U400 ExtraCellular Fluid Analyzer** |
| **Common / Classification Name:** | **Impedance Plethysmograph** |
| **Class:** | **II** |
| **Regulation Number:** | **870.2770** |
| **Panel:** | **Cardiovascular** |
| **Product Code:** | **DSB** |

**Labeling:**

Federal (United States) Law restricts this device to sale by or on the order of a physician or licensed healthcare professional.

**Predicate Device for Substantial Equivalence Comparison:**

The L-Dex® U400 ExtraCellular Fluid Analyzer, also referred to as the L-Dex U400 in the rest of this document, is claimed to be substantially equivalent to the following currently marketed Predicate Device and currently being marketed by ImpediMed Limited:

| Manufacturer | Device Name | 510-K Number | Decision Date |
|---|---|---|---|
| ImpediMed Limited | L-Dex® U400 ExtraCellular Fluid Analyzer | K080825 | Oct. 03, 2008 |

**Device Description:**

This premarket submission is to expand the previously cleared Indications for Use/Intended Use in the predicate device to include legs in women and men in addition to the predicate device clearance for arms in women, and clarify that it is for use on adult human patients.

The L-Dex® U400 ExtraCellular Fluid Analyzer like its predicate is a multi-frequency bioelectrical impedance analyzer. It is a non-invasive, battery powered extracellular fluid status analyzer.

The L-Dex® U400 accurately measures current, voltage and phase angle, calculates impedance, resistance and reactance as with its predicate. These measurements and calculations are used to estimate extracellular fluid (ECF) allowing for aiding in the assessment of the development of unilateral Lymphedema of the limbs.

**Indications for Use/Intended Use:**

A bioelectrical impedance analyzer/monitor for use on adult human patients, utilizing impedance ratios that are displayed as an L-Dex ratio that supports the measurement of extra cellular fluid volume differences between the limbs and is presented to the clinician on an L-Dex scale as an aid to their clinical assessment of unilateral lymphedema of the arm and leg in women and the leg in men.
The device is only indicated for patients who will have or who have had lymph nodes, from the axillary and pelvic regions, either removed, damaged or irradiated.
The device is not intended to diagnose or predict lymphedema of the 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.

**Contraindications for Use:**

Patients with active implanted medical devices, pregnant patients (unless under the guidance of a medical specialist), and patients undergoing external defibrillation.

Patients with allergies to electrode hydrogel, skin sensitivities to electrode hydrogel and skin breakdown in areas where the L-Dex electrode placement is required.

This device is contraindicated for use on compromised skin surfaces primarily due to the adherence of the EKG type electrodes used.

**Clinical Performance Data:**

Clinical Performance data in support of the expanded indications for use is included within this submission.

**Rationale for Substantial Equivalence:**

1. The L-Dex® U400 employs the same patient interface design as the predicate device.
2. The hardware and software of the L-Dex® U400 is identical in design, construction and manufacturer as the predicate device.
3. The operational features of the L-Dex® U400 are the same as those of the predicate device.
4. The safety features of the L-Dex® U400 are the same as those of the predicate device.

Therefore, in summary, the L-Dex® U400 ExtraCellular Fluid Status Analyzer is substantially equivalent to the predicate device.

**Safety and Effectiveness**

The L-Dex® U400 ExtraCellular Fluid Analyzer complies with the electrical standards for Safety and Electro Magnetic Compatibility / Immunity (EMC / EMI) in accordance with the International Standards IEC 60101-1 and IEC 60601-1-2. This testing to the low voltage directive and to emissions / immunity requirements for EMC/EMI requirements reasonably assures the device is safe when used as directed for its prescribed intended use.

The L-Dex® U400 ExtraCellular Fluid Status Analyzer does not raise any new issues of safety, effectiveness or performance of the device when compared to the existing predicate device.

**Conclusions:**

**The data submitted in this 510(k) Premarket Notification, for the L-Dex® U400 ExtraCellular Fluid Status Analyzer demonstrates that this product is substantially equivalent with respect to the indications for use, operating principles, operational features and safety features to the legally marketed predicate device. With the information provided, the safety and effectiveness of the product can be reasonably assured, and we believe that this device clearly meets the requirements for a "Substantial Equivalence" decision in accordance with the 510(k) guidelines.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

NOV - 4 2011

ImpediMed Limited
% Mr. Alden Kay
Vice President Quality & Regulatory
ImpediMed Limited
5959 Cornerstone Court West, Suite 100
SAN DIEGO CA 92121

Re: K100811
Trade/Device Name: L-Dex® U400 ExtraCellular Fluid Analyzer
Regulation Number: 21 CFR§ 870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: OBH
Dated: May 16, 2011
Received: May 18, 2011

Dear Mr. Kay:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Number:** K100811

**Device Name:** L-Dex® U400 ExtraCellular Fluid Analyzer

**Indications for Use/Intended Use:**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

**Prescription Use** __X__ **(Per 21 CFR 801.109)**

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K100811