



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

August 11, 2017

ImpediMed Limited
% Reuben Lawson
Senior Director, Regulatory Affairs and Clinical
ImpediMed Inc.
5900 Pasteur Court, Unit 125
Carlsbad, CA 92008

Re: K172122
Trade/Device Name: SOZO™
Regulation Number: 21 CFR§ 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: II
Product Code: OBH
Dated: July 13, 2017
Received: July 13, 2017

Dear Reuben Lawson:

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,


Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known)

K172122

Device Name **SOZO**TM

Indications for Use (Describe)

A bioimpedance spectroscopy device for use on adult human patients, utilizing impedance ratios that are displayed as an L-Dex ratio that supports the measurement of extracellular 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.

SOZOhub PC software – a PC software package that is intended to be used only with the ImpediMed SOZO device for uploading data on to the PC from the SOZO device, processing and analyzing of bioimpedance measurements.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human
Services Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA)
Staff PRASStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

510(k) SUMMARY

ImpediMed's SOZO system

Submitter:

ImpediMed Limited
Unit 1
50 Parker Court
Pinkenba Qld 4008
Australia

Phone: 760 585 2104

Facsimile: 760 804 9245

Contact Person: Reuben Lawson

Date Prepared: July 13, 2017

Name of Device: SOZO

Common or Usual Name: Body Fluid Analyzer

Classification Name: Impedance Plethysmograph

Regulatory Class: 21 CFR 820.2770

Product Code: OBH

Predicate Devices ImpediMed Limited's L-Dex[®] U400 (K130338)

Device Description

The SOZO system consists of a connected hand and footplate with built-in stainless steel electrodes, paired with an Android tablet over Bluetooth connection. An app ("SOZOapp"), supplied with the tablet, controls the functionality of the hardware and supplies the bioimpedance measurement data to a database ("SOZOhub") contained within the hospital/facility network.

Measurements require the patient to make contact with bare hands and feet on stainless steel electrodes. The measurement takes about 30 seconds, during which the SOZO system measures small quantities of electrical energy (200µa RMS) across 256 frequencies, spaced logarithmically from 3kHz to 1000kHz. Established algorithms are used to analyze data and calculate extracellular fluid impedance levels for left and right limbs, and present the impedance ratio as an L-Dex[®] score for the clinician to review. This score facilitates their clinical assessment of unilateral lymphedema of the arm and leg in woman, and the leg in men.

Intended Use/Indications for Use

A bioimpedance spectroscopy device for use on adult human patients, utilizing impedance ratios

that are displayed as an L-Dex ratio that supports the measurement of extracellular 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.

SOZOhub PC software – a PC software package that is intended to be used only with the ImpediMed SOZO device for uploading data on to the PC from the SOZO device, processing and analyzing of bioimpedance measurements.

Summary of Technological Characteristics

Bioimpedance spectroscopy is the technological principle for both the subject and predicate devices. The subject and predicate devices are based on the following same fundamental technological elements:

- Use of electrodes to take measurements; two ‘drive’ and two ‘sense’ channels are used to measure each side of the body;
- ‘Drive’ channels deliver very low levels of current (~200µa RMS) across 256 frequencies logarithmically spaced from 3kHz to 1000kHz;
- ‘Sense’ channels measure current (I), voltage (V) and phase angle (Ph), and calculates three bioimpedance parameters: impedance (Z), resistance (R) and reactance (Xc) to estimate extracellular fluid ratios, and calculate the impedance ratios which are converted to a L-Dex ratio;
- Data is stored in and accessed from a local database (SOZOhub) utilizing separate software installed on a network connected PC.

Minor technological differences exist between the subject and predicate devices:

- SOZO utilizes a revamped external housing, which is directly patient-contacting and uses stainless steel electrodes for taking bioimpedance measurements;
- SOZO is wall powered rather than battery powered;
- SOZO is controlled through an Android app on a supplied tablet, which is paired to the SOZO hardware over Bluetooth connection, and connects with the local database over Wi-Fi.

Purpose of 510(k)

The purpose of this 510(k) is to clear the design changes presented in the SOZO system.

These changes are intended to provide a faster, more streamlined customer experience with a more aesthetically pleasing design.

Performance Data

The SOZO system has gone through appropriate testing per design controls to confirm the new design's functionality and performance.

Electrical safety/EMC: testing was performed according to the requirements set forth in IEC 60601 (subparts -1, -1-2, and -1-6). It was determined that the SOZO device meets electrical safety and EMC requirements, and CB certificate was granted for the system.

Software V&V: the same level of concern software documentation as the predicate device was created and testing performed in accordance with ISO 62304. The software was verified and validated to meet acceptance criteria and perform as intended.

Biocompatibility: testing was performed by an accredited third party according to the requirements set forth in ISO 10993 for a low risk, limited contact device. It was determined that the SOZO system passed biocompatibility testing with no failures reported.

Comparative performance vs. predicate device: using a test fixture to create multiple fixed impedance loads representing different 'humans', a SOZO system was compared against a U400 system to verify correlation in L-Dex readings. The SOZO system showed a very strong correlation ($r > 0.99$) compared to the cleared U400 system.

Functional performance: multiple SOZO systems were tested for design reliability by repeatedly placing weights on the components that encounter the most physical stress. Testing showed that the system is expected to remain functional throughout its intended life.

Conclusions

The SOZO system has the same intended uses /indications, and similar technological characteristics, and principles of operation as its predicate device. In addition, the minor technological differences between the SOZO system and its predicate device raise no new or different issues of safety or effectiveness. Design controls demonstrate that the SOZO system is as safe and effective as the cleared device version. Thus, the SOZO system is substantially equivalent.

IX. PERFORMANCE STANDARDS

No performance standards or special controls have been developed under Section 514 of the FDC Act for a monitor of extracellular fluid (lymphedema) in an extremity. No special controls apply.

Consistent with FDA's guidance document entitled "*Use of Standards in Substantial Equivalence Determinations*" (March 12, 2000) and "*Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards*" (September 17, 2007), ImpediMed Limited is including this statement that the SOZO system complies with the following recognized consensus standards:

- IEC 60601-1:2005/A1:2012 General Electrical and Mechanical Safety;
- IEC 60601-1-2:2014 Ed4.0 Electromagnetic Compatibility;
- IEC 60601-1-6:2010/A1:2013 Usability
- EN/ISO 62304:2006 Medical device software - Software life-cycle processes;
- IEC 62366:2007/A1:2014 Application of usability engineering to medical devices;
- ISO 10993-1:2009/TC1:2010 Biological Evaluation of Medical Devices;
- ISO 10993-5:2009, Cytotoxicity;
- ISO 10993-10:2010, Test for Irritation and Skin Sensitization.

A Data Standards Form (FDA Form 3654) is provided in **Attachment 1** for each listed recognized consensus standard.