April 16, 2018

ImpediMed Limited
℅ Reuben Lawson
Senior Directory, Regulatory Affairs and Clinical
ImpediMed, Inc.
5900 Pasteur Court, Unit 125
Carlsbad, CA 92009

Re: K180126
Trade/Device Name: SOZO®
Regulation Number: 21 CFR§ 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: II
Product Code: OBH
Dated: January 12, 2018
Received: January 16, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180126

Device Name
SOZO®

Indications for Use *(Describe)*

The SOZO Body Fluid Analyzer has the following uses:

For adult human patients at risk of lymphedema:

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 volume differences between the limbs and is presented to the clinician on an L-Dex scale as an aid to their clinical assessment of lymphedema.

The use of the device to obtain an L-Dex score is only indicated for patients who will have or who have had lymph nodes, from the axillary and/or pelvic regions, either removed, damaged or irradiated.

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.

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510(k) SUMMARY
ImpediMed's SOZO® system

Submitter:

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Contact Person: Reuben Lawson

Date Prepared: April 12, 2018

Name of Device: SOZO®

Common or Usual Name: Body Fluid Analyzer

Regulation Number: 21 CFR§870.2770

Regulation Name: Impedance Plethysmograph

Regulatory Class: II

Product Code: OBH

Predicate Device: ImpediMed Limited's SOZO® (K172122)

Reference Devices: ImpediMed Limit's SOZO® (K172507)

ImpediMed Limited's SFB7™ (K052319)

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 applies small levels of electrical energy (200μA RMS) to the body across 256 frequencies spaced logarithmically from 3kHz to 1000kHz and measures the resulting voltage levels. 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 lymphedema in adult human patients..

Intended Use / Indications for Use

The SOZO body fluid analyzer has the following uses:

For adult human patients at risk of lymphedema:

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 volume differences between the limbs and is presented to the clinician on an L-Dex scale as an aid to their clinical assessment of lymphedema.

The use of the device to obtain an L-Dex score is only indicated for patients who will have or who have had lymph nodes, from the axillary and/or pelvic regions, either removed, damaged or irradiated.

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. SOZO is controlled through an Android app (“SOZOapp”) on a supplied tablet, which is paired to the SOZO hardware over Bluetooth connection, and connects with the SOZOhub local database over Wi-Fi.

Performance Data

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

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.

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.

Clinical testing: studies have identified the applicability of ImpediMed's BIS technology to act as an aid in the clinical assessment of bilateral lymphedema, by demonstrating strong correlation of extracellular fluid levels between at-risk and ipsilateral limbs (e.g. left leg vs. left arm).

Comparative performance vs. predicate device: using a test fixture to create multiple fixed impedance loads representing different 'humans', a SOZO system was compared against ImpediMed U400 and SFB7 system to verify correlation in outputs. The SOZO system showed a very strong correlation ($r > 0.99$) compared to both systems.

In all instances, the SOZO system functioned as intended and all results observed were as expected.

Conclusions

The SOZO system is as safe and effective as its predicate device. The SOZO system has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor software and labeling differences between the SOZO system and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the SOZO system is as safe and effective as its predicate device. Thus, the SOZO system is substantially equivalent.