April 19, 2021

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

Re: K203473
Trade/Device Name: SOZO
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: DSB
Dated: March 15, 2021
Received: March 17, 2021

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Carolyn Y. Neuland, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K203473

Device Name

SOZO®

Indications for Use *(Describe)*

The SOZO Body Fluid Analyzer is intended for adult patients living with heart failure.

This device is intended for use, under the direction of a physician, for the noninvasive monitoring of patients with fluid management problems suffering from heart failure. Data from the device should be considered in conjunction with other clinical data.

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

X Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) SUMMARY

ImpediMed's SOZO

Submitter

ImpediMed Limited
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Australia

Phone: 760 585 2104

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Contact Person: Reuben Lawson

Date Prepared: April 19, 2021

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: DSB

Predicate Device: ImpediMed Limited's SOZO (K193410)

Purpose of the Traditional 510(k) Notice

The purpose of the 510(k) is to clear modifications to the device including updates to software and labeling.

Indications for Use

The SOZO Body Fluid Analyzer is intended for adult patients living with heart failure. This device is intended for use, under the direction of a physician, for the noninvasive monitoring of patients with fluid management problems suffering from heart failure. Data from the device should be considered in conjunction with other clinical data.

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 ("MySOZO") managed on an external cloud-hosted database.

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 from 3kHz to 1000kHz and measures the resulting voltage levels.

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, intracellular fluid and total body water.
- Data is stored in and accessed from a cloud-based database (MySOZO) using a web browser interface. 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 MySOZO database over Wi-Fi.

Performance Data

The SOZO system has gone through appropriate testing per design controls to confirm functionality and performance of the 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: performance testing was undertaken using both fixed loads and human volunteers comparing modified to predicate SOZO measurements to demonstrate that outputs remained consistently accurate and precise.

Substantial Equivalence

The modified SOZO has the same intended use and similar indications, principles of operation, and technological characteristics as its predicate device. The following difference in the modified SOZO device's technological characteristics do not raise any new questions of safety or effectiveness:

- Modification to SOZOapp Fluid Analysis module, renaming it as the 'HF-Dex' module and incorporating a set of normative reference ranges to aid the clinician in their fluid management of patients living with heart failure.

Thus, the modified SOZO is substantially equivalent to its predicate devices.

Conclusions

Testing discussed above demonstrates that the modified SOZO device is as safe and effective, and performs as well as or better than the predicate device.