October 17, 2023

ImpediMed Limited
Richard Hines
Senior Manager of Regulatory Affairs
5900 Pasteur Court, Unit 125
Carlsbad, California 92008

Re: K232089
Trade/Device Name: SOZO Pro
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: II
Product Code: DSB
Dated: June 5, 2023
Received: July 19, 2023

Dear Richard Hines:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Gema Gonzalez -S

Maura Rooney
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232089

Device Name
SOZO Pro

Indications for Use *(Describe)*
The SOZO Pro 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.

The SOZO Pro 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.

The SOZO Pro may be used as an adjunct to existing methods by aiding clinicians who are using Subjective Global Assessment (SGA) tools to assess patients at risk of protein-calorie malnutrition (PCM).
The SOZO Pro may be further used to estimate the following body composition parameters in humans to track clinically relevant body composition parameters over time:
- Fat mass
- Fat-free mass
- Total body water
- Intracellular fluid
- Extracellular fluid
- Skeletal muscle mass

The following outputs are also presented:
- Body Mass Index (BMI)
- Basal metabolic rate (BMR; based on Mifflin – St. Jeor's algorithm) displayed in calories per day
- Protein and mineral (also known as 'dry lean mass') represents the content of a body that is not fat or fluid; calculated by subtracting total body water weight from fat-free mass weight.

The SOZO Pro device measures current (I), voltage (V) and phase angle (Phi), and from these values calculates resistance (R), reactance (Xc), and impedance (Z), which are used to estimate the above body composition parameters. The device/ software will also display the Cole plot, subject height, weight, age and sex.

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.

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"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."

Traditional 510(k)
SUMMARY

ImpediMed SOZO Pro

Submitter

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Contact Person: Richard Hines
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Date Prepared: August 30, 2023

Name of Device: SOZO Pro®

Common or Usual Name	Body Fluid Analyzer
Regulation Number	21 CFR §870.2770
Regulation Name	Impedance Plethysmograph
Regulatory Class	II
Product Code:	DSB (Cardiac Electrophysiology, Diagnostics and Monitoring)
Predicate Device:	SOZO® (K203473)
Reference Device #1:	SOZO Pro (K230530)
Reference Device #2:	SOZO Pro (K230531)
Reference Device #3:	Bodyport Cardiac Scale (K211585)

Purpose of the Special 510(k) Notice

The purpose of the 510(k) is to clear the SOZO Pro device which is a modification of the predicate K203473 SOZO device to include a weight scale to allow for patient weights to be measured directly with the device, along with updates to the stand hardware and electrodes. Software updates were included to integrate the scale and weight measurement capabilities.

Indications for Use

The SOZO Pro has the following uses:

The SOZO Pro 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.

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.

The SOZO Pro may be used as an adjunct to existing methods by aiding clinicians who are using Subjective Global Assessment (SGA) tools to assess patients at risk of protein-calorie malnutrition (PCM).
The SOZO Pro may be further used to estimate the following body composition parameters in humans to track clinically relevant body composition parameters over time:
• Fat mass
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• Skeletal muscle mass
The following outputs are also presented:
• Body Mass Index (BMI)
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• Protein and mineral (also known as 'dry lean mass') represents the content of a body that is not fat or fluid; calculated by subtracting total body water weight from fat-free mass weight.
The SOZO Pro device measures current (I), voltage (V) and phase angle (Phi), and from these values calculates resistance (R), reactance (Xc), and impedance (Z), which are used to estimate the above body composition parameters. The device/ software will also display the Cole plot, subject height, weight, age and sex.

Device Description

The SOZO Pro 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. Patient weight is measured with load cells located in the SOZO Pro foot unit or can be hand entered.

Bioimpedance measurements require the patient's weight to be measured by a scale embedded in the base of the system or for the weight of the patient to be entered manually. Following the collection of the patient weight, the patient contacts the SOZO Pro with their bare hands and feet on stainless steel electrodes. The impedance measurement takes about 30 seconds, during which the SOZO Pro® 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 channels are used to measure each side of the body.

- Delivery of very low levels of current (200µA RMS) across 256 frequencies logarithmically spaced from 3kHz to 1000kHz.

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

Performance Data
The SOZO Pro 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 Pro device meets electrical safety and EMC requirements, and CB certificate was granted for the system.

Software V&V: the SOZO Pro 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 patient contact areas of SOZO Pro system passed biocompatibility testing with no failures reported as they are unchanged from the predicate.

Functional performance: performance testing was undertaken using fixed loads and comparing modified SOZO Pro to predicate SOZO measurements to demonstrate that outputs remained consistently accurate and precise.

Weight Scale Verification: Scale verification testing for SOZO Pro was performed in accordance with the *NIST Handbook 44* (2022 Edition) and *EU Directive 2014/31/EU* for non-automatic weighing instruments. Scale verification testing experienced no failures.

Active implantable pacemakers and ICD compatibility: SOZO Pro illustrated compatibility to a variety of pacemakers and implantable cardioverter defibrillators per the test methods described in ISO 14117.

Substantial Equivalence

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

Conclusions

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