



May 4, 2023

ImpediMed Limited  
% Richard Hines  
Senior Manager of Regulatory Affairs  
5900 Pasteur Court, Ste. 125  
Carlsbad, CA 92008

Re: K230531  
Trade/Device Name: SOZO Pro  
Regulation Number: 21 CFR§ 870.2770  
Regulation Name: Impedance plethysmograph  
Regulatory Class: II  
Product Code: QJB, DSB, MNW  
Dated: April 7, 2023  
Received: April 7, 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 (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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Gema Gonzalez -S**

Gema Gonzales, MS  
Acting 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

## Indications for Use

510(k) Number (if known)

K230531

Device Name

SOZO Pro

Indications for Use (Describe)

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.

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**510(k) SUMMARY**

**ImpediMed SOZO Pro**

**Submitter**

ImpediMed Limited  
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Australia

**Phone:** 760 585 2104

**Facsimile:** 760 804 9425

**Contact Person:** Richard Hines  
**Contact Email:** rhines@impedimed.com

**Date Prepared:** February 20, 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:** QJB, DSB, MNW (Adjunct Monitor, Protein Calorie Malnutrition)

**Predicate Device:** SOZO® (K190529)

**Reference Device:** SOZO® (K193410)

**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 K190529 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 system 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 system 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.

## 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 reference.

**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.

### **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.