



November 25, 2019

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

Re: K190529  
Trade/Device Name: SOZO®  
Regulation Number: 21 CFR 870.2770  
Regulation Name: Impedance plethysmograph  
Regulatory Class: II  
Product Code: QJB, DSB, MNW  
Dated: October 24, 2019  
Received: October 24, 2019

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/pmnmn.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,

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

## Indications for Use

510(k) Number (if known)

K190529

Device Name

SOZO®

Indications for Use (Describe)

The SOZO 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 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 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's SOZO® system**

**Submitter:**

ImpediMed Limited  
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Australia

Phone: 760 585 2104  
Facsimile: 760 804 9245

Contact Person: Reuben Lawson

Date Prepared: November 25, 2019

**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 Codes:** QJB, DSB, MNW  
**Predicate Device:** ImpediMed Limited's SOZO (K172507); ImpediMed Limited's IMP SFB7 (K052319)  
**Reference Devices:** ImpediMed Limited's SOZO (K172122; K180126)

**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<sup>®</sup> system applies small levels of electrical current (200 $\mu$ A 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 various body composition parameters and present the outputs for the clinician to review.

### **Intended Use / Indications for Use**

The SOZO<sup>®</sup> Body Fluid Analyzer is intended for the following uses:

The SOZO 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 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 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.

### **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 (200 $\mu$ A RMS) across 256 frequencies logarithmically spaced from 3kHz to 1000kHz;
- 'Sense' channels measure current (I), voltage (V) and phase angle (Ph), and calculate three bioimpedance parameters: impedance (Z), resistance (R) and reactance (Xc) to estimate impedance levels at different frequencies and use established algorithms to calculate body composition parameters;
- Data is stored in and accessed from a local database (SOZOhub) utilizing separate software installed on a network connected PC.

Thus, SOZO is the same as its predicate SOZO device. The technological characteristics of the SOZO system and equivalence to the reference SFB7 system have previously been reviewed by FDA in K172122, K172507, and K180126.

### 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:** clinical studies have identified the applicability of ImpediMed's BIS technology to act as an aid in body composition.

**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's SFB7 system to verify correlation in outputs. The SOZO system showed a very strong correlation ( $r > 0.99$ ) compared to outputs from the SFB7 device.

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. 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.