January 28, 2026

Impedimed Limited
Richard Hines
Senior Manager of Regulatory Affairs
Unit 1
50 Parker Court Pinkenba
Pinkenba, QLD 4008
Australia

Re: K253224
Trade/Device Name: MySOZO Software version 6.0.1.2 (SW version 6.0.1.2)
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II
Product Code: DSB, OBH, MNW
Dated: December 21, 2025
Received: December 29, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

MAURA ROONEY -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253224

Please provide the device trade name(s).

MySOZO Software version 6.0.1.2

Please provide your Indications for Use below.

MySOZO Software version 6.0.1.2 has the following uses:

The MySOZO Software version 6.0.1.2 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 MySOZO Software version 6.0.1.2 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 MySOZO Software version 6.0.1.2 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 MySOZO Software version 6.0.1.2 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Traditional 510(k)
SUMMARY

ImpediMed MySOZO Software Version 6.0.1.2

Submitter

ImpediMed Limited
Unit 1
50 Parker Court
Pinkenba, Qld 4008
Australia

Phone: 760 585 2104

Facsimile: 760 804 9425

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

Date Prepared: September 23, 2025

Name of Device: MySOZO Software Version 6.0.1.2

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 Pro® (K232089)
Reference Device: SOZO(K180126)

Purpose of the Traditional 510(k) Notice

The purpose of the 510(k) is to clear the MySOZO Software Version 6.0.1.2, which is the system software of the predicate K232089 SOZO Pro and the reference device, K180126 SOZO. MySOZO Software Version 6.0.1.2 includes verification and validation testing that incorporates updates to align the web browser and tablet application user interface (version 6.0), update to a runtime application and the hardening of the Bluetooth connectivity capabilities (version 6.0.1) and an update to the (version 6.0.1.2) bilateral L-Dex Assessment.

Indications for Use

MySOZO Software version 6.0.1.2 has the following uses:

The MySOZO Software version 6.0.1.2 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 MySOZO Software version 6.0.1.2 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 MySOZO Software version 6.0.1.2 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 MySOZO Software version 6.0.1.2 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

MySOZO Software version 6.0.1.2 is the cloud-based software component of the overall ImpediMed SOZO Digital Health Platform device system. SOZO Digital health platform consists of several elements. MySOZO Software allows for bioimpedance measurements to be made with either the predicate (K232089) SOZO Pro or the reference (K180126) SOZO device.

Bioimpedance measurements are facilitated via the MySOZO Software with either the SOZO Pro or SOZO devices, which allows clinicians to evaluate patient fluid levels. Following the collection of the patient data (e.g., weight, height, dominant limb, age), the patient contacts the SOZO or SOZO Pro with their bare hands and feet on the stainless-steel electrodes. The MySOZO Software version 6.0.1.2 impedance measurement takes about 30 seconds, during which the SOZO or SOZO Pro®, 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. MySOZO Software transmits the impedance data to the database, calculates the values, and retrieves and displays the results upon request.

Technological Characteristics

Bioimpedance spectroscopy software allows for data and is the technological principle by both the subject and predicate devices can measure patient fluid status. The subject and predicate devices are based on the following same fundamental technological elements:

- MySOZO Software version 6.0.1.2 data is stored in and accessed from a cloud-based database (MySOZO) using a web browser interface. SOZO or SOZO Pro are controlled through an iOS or Android app ("SOZOapp") on a tablet computer, which is paired over a Bluetooth connection and connects with the MySOZO Software version 6.0.1.2 database over Wi-Fi.

- MySOZO Software version 6.0.1.2 is the software and database application that facilitates the SOZO Digital Health Platform devices (SOZO or SOZO Pro) to conduct bioimpedance measurements for patients at risk of the diseases identified in the indication for use statement.

MySOZO Software Verification

MySOZO Software Version 6.0
MySOZO Software Version 6.0, a software update to align the web browser and tablet application user interface and to ensure portability of patient information from one MySOZO software clinic to another. Verification and validation testing confirmed the performance of the software.

MySOZO Software Version 6.0.1
MySOZO Software Version 6.0.1 was an update to the software to include the latest version of a runtime application and a reinforcement of Bluetooth technology software. Verification and validation confirmed the performance of the software.

MySOZO Software Version 6.0.1.2
MySOZO Software Version 6.0.1.2 provides an update to the MySOZO L-Dex assessment module for patients at risk of bilateral lymphedema. Algorithm and software verification and validation confirmed the performance of the software.

Substantial Equivalence
MySOZO Software Version 6.0.1.2 has the same intended use and indication for use statement, facilitates the same principles of operation, and technological characteristics as its predicate device. The differences in the MySOZO Software Version 6.0.1.2 design characteristics to the predicate SOZO Pro device do not raise any new questions of safety or effectiveness:

Conclusions
Testing discussed above demonstrates that the MySOZO Software Version 6.0.1.2 device is safe and effective and performs as intended to assist in the intended performance and use of the predicate SOZO Pro (K232089) and reference SOZO (K180126) devices.