August 17, 2026

ImpediMed Limited
Chris Kyung
Senior Manager of Regulatory Affairs
Suite 31c
12-18 Tryon Rd.
Lindfield, NSW 2070
Australia

Re: K260224
Trade/Device Name: MySOZO Software version 6.1.0.1 (SW version 6.1.0.1)
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II
Product Code: DSB, MNW, QJB
Dated: July 15, 2026
Received: July 16, 2026

Dear Chris Kyung:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.	K260224 ?

Please provide the device trade name(s). ?

MySOZO Software version 6.1.0.1 (SW v6.1.0.1)

Please provide your Indications for Use below. ?

The MySOZO Software version 6.1.0.1 (SW Version 6.1.0.1) 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 6.1.0.1(SW Version 6.1.0.1) 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), and to aid in assessing patients at risk of sarcopenia, a disease of low muscle mass or muscle loss. The MySOZO Software version 6.1.0.1 (SW Version 6.1.0.1) 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 mass index (FMI)
• Fat-free mass• Total body water
• Intracellular fluid
• Extracellular fluid
• Skeletal muscle mass (SMM)
• Skeletal muscle mass index (SMMI)

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 6.1.0.1 (SW Version 6.1.0.1) 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)	?
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)	?

Traditional 510(k)
SUMMARY

MySOZO Software Version 6.1.0.1 (SW Version 6.1.0.1)

Submitter:	Impedimed Limited Suite 31C, 12-18 Tryon Rd, Lindfield NSW, 2070, Australia
Phone:	760 585 2104
Fax:	760 804 9425
Contact Person:	Chris Kyung
Contact Email:	ckyung@impedimed.com
Date Prepared:	August 12, 2026
Name of Device:	MySOZO Software Version 6.1.0.1 (SW Version 6.1.0.1)
Common or Usual Name:	Body Fluid Analyzer
Regulation Number:	21 CFR 870.2770
Regulation Name:	Impedance Plethysmograph
Regulatory Class:	II
Product Code:	DSB, QJB, MNW
Predicate Device:	SOZO Pro® (K232089)
Reference Device:	SOZO (K190529)

Purpose of the Traditional 510(k) Notice

The purpose of the 510(k) is to clear the MySOZO Software Version 6.1.0.1 (SW Version 6.1.0.1), which is the system software of the predicate K232089 SOZO Pro and the reference device, K190529 SOZO. MySOZO Software Version 6.1.0.1 (SW Version 6.1.0.1) 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 6.1.0.1) Body Comp assessment module.

Indications for Use

The MySOZO Software version 6.1.0.1 (SW Version 6.1.0.1) has the following uses:

The MySOZO Software version 6.1.0.1 (SW Version 6.1.0.1) 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 6.1.0.1 (SW Version 6.1.0.1) 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), and to aid in assessing patients at risk of sarcopenia, a disease of low muscle mass or muscle loss.

The MySOZO Software version 6.1.0.1 (SW Version 6.1.0.1) 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 mass index (FMI)*
- *Fat-free mass*
- *Total body water*
- *Intracellular fluid*
- *Extracellular fluid*
- *Skeletal muscle mass (SMM)*
- *Skeletal muscle mass index (SMMI)*

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 6.1.0.1 (SW Version 6.1.0.1) 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

Device Design

MySOZO Software Version 6.1.0.1 (SW Version 6.1.0.1) is the cloud-based software component of the predicate device.

Principles of Operation

Bioimpedance measurements are facilitated via the MySOZO Software Version 6.1.0.1 (SW Version 6.1.0.1) with either the SOZO Pro or SOZO devices, which allow 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. MySOZO Software Version 6.1.0.1 (SW Version 6.1.0.1) 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 Version 6.1.0.1 (SW Version 6.1.0.1) transmits the impedance data to the database, calculates the values, and retrieves and displays the

results upon request.

MySOZO Software Version 6.1.0.1 (SW Version 6.1.0.1) Bioimpedance Assessments
MySOZO Software version 6.1.0.1 (SW Version 6.1.0.1) consists of several different bioimpedance assessment types that provide impedance data for a multitude of indications and diseases including heart failure, lymphedema, protein calorie malnutrition, and sarcopenia.

Technological Characteristics
MySOZO Software version 6.1.0.1 (SW Version 6.1.0.1) allows for data creation and is the technological principle by which 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 6.1.0.1 (SW Version 6.1.0.1) has the same intended use and a similar IFU statement to the predicate device. These IFU statement differences do not raise new concerns for safety and effectiveness.
- MySOZO Software version 6.1.0.1 (SW Version 6.1.0.1) data is stored in and accessed from a cloud-based database (MySOZO) using a web browser interface. SOZO Pro (predicate device) and SOZO (reference device) 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 6.1.0.1 (SW Version 6.1.0.1) database over Wi-Fi.
- MySOZO Software version 6.1.0.1 (SW Version 6.1.0.1) is the software and database application that facilitates the SOZO Pro (Predicate Device) and SOZO (Reference Device) to conduct bioimpedance measurements for patients at risk of the diseases identified in the indication for use statement.
- MySOZO Software version 6.1.0.1 (SW Version 6.1.0.1) facilitates measure of 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.

Conditions of Use
The subject device software, MySOZO Software version 6.1.0.1 (SW Version 6.1.0.1) is designed for use in a clinical environment for patients with heart failure, who need their body composition metrics measured, or patients who have had lymph nodes (axillary and/or pelvic) removed, damaged, or irradiated.

The bioimpedance devices (K190529 and K232089) SOZO / SOZO Pro require designated patients to contact the device electrodes simultaneously with their bare hands and feet via the device hand and foot units. The SOZO / SOZO Pro transmits current (between 3kHz and 1000kHz) to the patient and measures bioimpedance and compares fluid levels in specific limbs likely or other anatomies likely to experience changes in fluid status over time.

A clinician communicates with the SOZO / SOZO Pro bioimpedance device(s) by utilizing an iOS or Android tablet to send instructions back to the SOZO / SOZO Pro device(s) via the SOZOapp, such as when to take a bioimpedance measurement, or to which patient profile to assign the measured bioimpedance data. The tablet software app allows the clinician to view and utilize current and historic bioimpedance patient data (LDex, HF-Dex, and Body Composition scores) to assist physicians in making clinical assessments about specific patient's impedance condition. All impedance calculations are made, and data are stored in a cloud-based AWS hosted database via the MySOZO Software version 6.1.0.1 (SW Version 6.1.0.1), the subject device.

Clinical Verification of Diseases of Muscle Loss
MySOZO Software version 6.1.0.1 (SW Version 6.1.0.1) illustrates clinically acceptable body composition assessment when appropriate method-specific thresholds are applied. MySOZO Software version 6.1.0.1 showed balanced diagnostic performance with acceptable sensitivity and specificity for identification of muscle loss that may be indicative of sarcopenia.

MySOZO Software Verification

MySOZO Software Version 6.0 (SW Version 6.0)
MySOZO Software Version 6.0 (SW 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 (SW Version 6.0.1)
MySOZO Software Version 6.0.1 (SW 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 6.1.0.1 (SW Version 6.1.0.1)
MySOZO Software version 6.1.0.1 (SW Version 6.1.0.1) provides an update to the MySOZO Body Comp assessment module with new colored reference ranges for a few of the existing metrics. Other new metrics (SMMI, FMI, ASMM) were added to the Body Comp assessment module. Verification and validation confirmed the performance of the software.

Substantial Equivalence
MySOZO Software version 6.1.0.1 (SW Version 6.1.0.1) has the same intended use and a similar indication for use statement to the predicate, facilitates the same principles of operation, and technological characteristics as its predicate device. The differences in MySOZO Software version 6.1.0.1 (SW Version 6.1.0.1) design characteristics to the predicate SOZO Pro device do not raise any new questions of safety or effectiveness.

Conclusions
Testing discussed above demonstrates that MySOZO Software version 6.1.0.1 (SW Version 6.1.0.1) 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 (K190529) devices.