October 16, 2025

Mode Sensors AS
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K243727
Trade/Device Name: Re:Balans
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II
Product Code: DSB
Dated: June 16, 2025
Received: June 16, 2025

Dear Prithul Bom:

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,

Hetal B. Odobasic -S

for

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular 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: 0MB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243727

Device Name

Re:Balans

Indications for Use *(Describe)*

The Re:Balans is intended for use under the direction of a physician, for the non-invasive monitoring of patients with fluid management-related health conditions. The device measures thoracic bioimpedance in patients to assist the physician in fluid management assessment.

The device is indicated for adult patients with fluid overload such as end-stage renal disease, and patients at risk of dehydration.

The device does not generate any real-time alarms for consideration by the user at home or by a healthcare professional. Data from the device should be used in the context of all clinical data to make determinations of a patient's fluid status.

Type of Use *(Select one* or *both,* as *applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

510(k) Owner/ Submitter	Mode Sensors AS, Professor Brochs Gate 2, 7030 Trondheim, Norway
Date Prepared:	8th of March 2024
Contact Person:	Magnus Nordahl P: + 47 404 34 018 E: regulatory@modesensors.com
Classification name:	Impedance Plethysmograph
Device Type/ Common Name:	Plethysmograph, Impedance
Trade Name:	Re:Balans
Class	Class II
Product Code:	DSB
Classification Regulation:	870.2770
Predicate Device:	IMED-Z Fluid Status Monitor, K142503 The predicate has not been subject to a design-related recall.
Reference Device:	ImpediMed Limited's SFB7, K052319

Device Description

The Re:Balans is a non-invasive wearable device measuring impedance in patients with fluid management-related health conditions.

The device has the form factor of an adhesive patch, with four integrated electrodes, which is applied on the back of the patient. The impedance signal is obtained by applying a small, safe battery-generated current and measuring the resulting electrical impedance.

The impedance signal reflects the electrical resistance of the tissue and is modulated by the changes in fluid levels. The impedance signal is captured at multiple unique frequencies to enable the calculation of base impedance, extracellular and total resistance values. The Impedance decreases when fluid increases and increases when fluid decreases in the thorax. Normal upper body base impedance range is between 35– 65 Ohms. However, every person has their own baseline values. Fluid status changes should be noted and shared with professional medical clinicians when impedance readings vary from typical daily values.

Once the device is successfully placed and activated on the patient, the Re:Balans will collect impedance data over a period of up to 7 days. Re:Balans is a medical electrical equipment, non-sterile, and single-use device for intact skin only. Re:Balans is designed for use in clinic and home settings.

The data readout is performed on the Re:Balans software application compatible with iOS iPad.

The Re:Balans device is an assessment tool. It is not intended to be a medical diagnostic device. This monitor is intended to be operated by technically qualified medical personnel.

The physician or designated healthcare provider is responsible for interpreting what assessment, intervention, or action is required as a result of changing impedance values.

Intended Use/Indications for Use

The Re:Balans is intended for use under the direction of a physician, for the non-invasive monitoring of patients with fluid management-related health conditions. The device measures thoracic bioimpedance in patients to assist the physician in fluid management assessment.

The device is indicated for adult patients with fluid overload such as end-stage renal disease, and patients at risk of dehydration.

The device does not generate any real-time alarms for consideration by the user at home or by a healthcare professional. Data from the device should be used in the context of all clinical data to make determinations of a patient's fluid status.

Technological Characteristics

Both the Subject Device and Predicate Device are bioimpedance measurement devices designed to assess fluid status by the measurement of electrical impedance on the back of the patient's torso. They share the same intended uses, indications, device characteristics, body placement, including

prescription-only designation, suitability for both home and clinical settings, device output in Ohms, and the same electrode geometry/components. The differences identified between the Subject Device and its Predicate Device does not introduce any new concerns, as the Subject Device has been thoroughly tested to ensure its safety and performance.

A summary table is included for reference:

Description	Subject Device	Predicate	Comparison
Device Name	Re:Balans	IMED-Z Fluid Status Monitor	N/A
510(k) Number	K243727	K142503	N/A
Product Code Reference	DSB	DSB	Same
Intended Use / Indications for Use	The Re:Balans is intended for use under the direction of a physician, for the non-invasive monitoring of patients with fluid management-related health conditions. The device measures changes in thoracic bioimpedance in patients to assist the physician in fluid management assessment. The device is indicated for adult patients with fluid overload such as end-stage renal disease, and patients at risk of dehydration. The device does not generate any real-time alarms for consideration by the user at home or by a healthcare professional. Data from the device should be used in the context of all clinical data to make determinations of a patient's fluid status.	The IMED-Z Fluid Status Monitor is intended for patients: • With fluid management problems • Taking diuretic medication • Living with Heart Failure • Living with End-stage renal disease • Recovering from Coronary artery Disease related event • Suffering from Recurrent Dehydration This device is intended for use, under the direction of a physician, for the non-invasive monitoring and management of patients with fluid management problems in a variety of medically accepted clinical applications.	No clinical difference. Both devices are indicated for non-invasive monitoring and management of patients with fluid management problems. The Subject Device's indications for use are narrower than the predicate. This has no impact on the substantial equivalence as the Subject Device's proposed indications are included in the predicate indications.
Prescription Only	Yes	Yes	Same
Intended Use Environment	Home and clinical environment	Home and clinical environment	Same
Patient Age	Above 21 years (adults)	Above 21 years (adults)	Same
Principle of Operation	Impedance measurements at 45 microamperes at 104 kHz. In addition, multiple frequencies enable calculation of impedance values that represent extracellular resistance (RE) and total resistance (RT).	Impedance measurements at 2 milliampere at 100 kHz	Similar The Subject Device performs bioimpedance measurements in the same manner with lower applied electrical currents at multiple frequencies instead of one. The Subject Device includes similar measurements at 104kHz as the predicate. The use of multiple frequencies also enables calculation of impedance values that represent extracellular and total resistance in addition to the 104 kHz measurement.

			This does not raise new questions of safety and effectiveness.
Device Output(s)	104 kHz in ohms Additional outputs: • Extracellular Resistance (in Ohms) • Total Resistance (in Ohms)	100 kHz in ohms	Similar. This does not raise new questions of safety and effectiveness. 100 kHz and 104 kHz provide same results in bench performance testing. The differences are frequencies has minimal impact on safety and effectiveness. The additional outputs are calculated impedance values representing extracellular resistance and total resistance and has minimal impact on safety and effectiveness.
Measurement area / device placement	Torso, covering the trapezius, rhomboid major, and erector spinae muscles	Torso, covering the trapezius, rhomboid major, and erector spinae muscles	Same
Wear time	Up to 7 days	The skin contacting components are intended for a duration of up to 24 hours.	The Subject Device is intended for up to 7 days wear and the predicate is tested for up to 24 hours wear. The Subject Device has been biocompatibility tested and is considered safe for prolonged use on intact skin, and the data collection performance is measured to be reliable based in non-clinical performance testing. This does not raise new questions of safety and effectiveness.
Electrode connection geometry / components	4-point (tetrapolar), wet hydrogel (ECG style), single-use.	4-point (tetrapolar), wet hydrogel (ECG style), single-use.	Same
Data Transmission	Wireless transfer, Bluetooth Low Energy	Cable	The Subject Device has wireless transfer. The wireless function is designed and tested to maintain security, safety and performance for its intended use. This does not raise new questions of safety and effectiveness.
System Requirements and Device Readout	Readout on the Re:Balans iOS app.	Readout on the IMED-Z acquisition module display	The readout of the Subject Device data is performed on a proprietary app installed on iOS iPad. This does not raise new questions of safety and effectiveness as both devices enables immediate readout after measurements.
Energy Source	Battery-powered, 3V coin cell battery on device	Battery-powered, AA alkaline batteries	The device safety is tested and in compliance to recognized standards for electrical safety. This has no functional difference; the energy source difference does not affect safety or effectiveness.

Ingress Protection	IP54	IP20	Similar. Subject Device provides enhanced ingress protection.
Type BF degree of protection	Yes	Yes	Same
Relevant Performance and Safety Standards	IEC 60601-1-11:2015 IEC 60601-1-11:2015/AMD1:2020 IEC 60601-1-2:2014 IEC 60601-1-2:2014/AMD1:2020 IEC 60601-1-6:2010 IEC 60601-1-6:2010/AMD1:2013 IEC 60601-1-6:2010/AMD2:2020 IEC 60601-1:2005 IEC 60601-1:2005/AMD1:2012 IEC 60601-1:2005/AMD2:2020 IEC 62304:2006 IEC 81001-5-1:2021 ISO 14155:2020 ISO 10993-1 ISO 10993-23 ISO 10993-5 ISO 10993-10 IEC 62366-1 ISO 10993-11:2017 ASTM D4169-22 AAMI TIR57:2016 AAMI TIR69:2017 (R2020)	IEC 60601-1 Ed 3.1 IEC 60601-1-2 Ed 3.0 (2007-03) ISO 10993-1 ISO 10993-23 ISO 10993-5 ISO 10993-10	Similar. The Subject Device has undergone additional testing

Performance Data

The subsequent chapters include the testing performed on the Subject Device to support the substantial equivalence determination.

Non-Clinical Performance Testing

Biocompatibility Testing

Biocompatibility evaluation and testing of Re:Balans for relevant endpoints was provided as recommended by FDA's Guidance for Industry and FDA Staff, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", September 8, 2023. Based on applicable endpoints, the Subject Device was tested for Cytotoxicity, Sensitization, and Irritation. The device is determined safe for the intended use on intact skin and prolonged use.

EMC, Wireless, Electrical, Mechanical, and Thermal Safety

Electrical safety and electromagnetic compatibility (EMC) testing were conducted on the Re:Balans. The device complies with the requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment:

IEC 60601-1-11:2015
IEC 60601-1-11:2015/AMD1:2020
IEC 60601-1-2:2014
IEC 60601-1-2:2014/AMD1:2020
IEC 60601-1-6:2010
IEC 60601-1-6:2010/AMD1:2013
IEC 60601-1-6:2010/AMD2:2020
IEC 60601-1:2005
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

Additionally, a coexistence evaluation was performed per AAMI TIR69:2017, "Risk management of radio- frequency wireless coexistence for medical devices and systems", identifying the Re:Balans as "Category D" – negligible wireless risk, no significant risk – and requiring no additional coexistence testing.

Device Firmware

The firmware was developed, tested, and documented in accordance with IEC 62304:2006 - Medical device software - Software life cycle processes, and risk assessed according to ISO 14971:2019. The documentation was compiled and submitted based on the 'Basic Documentation Requirements consistent with the 'Content of Premarket Submissions for Device Software Functions, June 2023'.

Human Factors Engineering

The Re:Balans device is confirmed safe and effective for its intended use and environments, meeting the standards of IEC 60601-1-6:2010 and its amendments (AMD1:2013 and AMD2:2020) for medical electrical equipment usability, basic safety, and essential performance. In addition, a Human Factors Engineering Report is provided as recommended by FDA's Guidance for Industry and FDA Staff, "Applying Human Factors and Usability Engineering to Medical Devices", February 3, 2016.

Performance Bench Testing

A bench test was conducted to evaluate the multi-frequency impedance measurement performance of the Subject Device. The Subject Device demonstrates accurate and consistent impedance measurement performance.

Shelf-life Testing

An accelerated aging test was conducted on the Re:Balans patch and packaging by an accredited third-party. The data collected supports the claimed shelf-life.

Radio Frequency Spectrum Efficiency

The Subject Device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules; 15.105(b) Class B Digital Device.

Cybersecurity

The device firmware's cybersecurity was developed, tested, and demonstrated to be effective as per the FDA's recommended Guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, September 27, 2023" and IEC 81001-5-1:2021.

Software app

The Re:Balans iOS app was developed, tested, and documented based on the "FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", and "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions".

Shipping and Packaging Testing

Transport testing was performed on Re:Balans packaging including final device samples. The testing followed ASTM D4169-22. Results demonstrated that the function of Re:Balans is not adversely affected during transportation.

Clinical Data

Analysis of clinical data from two studies demonstrated the utility of the Re:Balans measurements for monitoring patients with fluid management problems:

Study Data	**Investigation #1**	**Investigation #2**
Study Title	REO	DELAGE
Level of Evidence	Single-arm study with subjects serving as own control	Observational study
Location	Outside of United States	Outside of United States
Description	Healthy volunteers were continuously monitored by Re:Balans during furosemide-induced dehydration.	Patients with end-stage renal disease undergoing regular haemodialysis were continuously monitored by Re:Balans for ~3 weeks.
Study Design	Prospective, experimental, non-randomized	Prospective, observational, non-randomized
Effectiveness	The change in device parameters (Base Impedance, RE and RT correlated inversely with fluid loss (e.g. urine elimination) during dehydration	The change in device parameters (Base Impedance, Re and Rt) correlated inversely with weight change throughout the 3-week monitoring period.
Safety	Four device-related adverse events (minor/negligible skin irritations) from a total of 37 device exposures.	No device-related adverse events from a total of 53 device exposures.
Summary	The investigation demonstrates that Re:Balans is very sensitive to dehydration and supports the indication for use 'patients at risk of dehydration'.	The investigation demonstrates that Re:Balans monitors fluid volume changes in patients with chronic kidney disease and supports the indication for use 'fluid overload such as end-stage renal disease'.

Conclusion

The Company (Mode Sensors AS) has demonstrated that the Re:Balans, as described in this submission, demonstrates substantial equivalence because the fundamental technology, operating principles and intended use are the same as the predicate device. The summary data provide reasonable assurance of safety and effectiveness of the Re:Balans System by demonstrating substantial equivalence to its predicate. As supported by the descriptive information, verification, validation, and compliance testing, the Re:Balans is substantially equivalent to the predicate device.