November 24, 2025

Fresenius Medical Care Renal Therapies Group, LLC
Christopher Doherty
Regulatory Affairs Fellow
920 Winter St
Waltham, Massachusetts 02451

Re: K250634
Trade/Device Name: BCM2-Body Composition Monitor
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II
Product Code: DSB
Dated: October 27, 2025
Received: October 27, 2025

Dear Christopher Doherty:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250634

Device Name

BCM2-Body Composition Monitor

Indications for Use *(Describe)*

The BCM2 is intended for use, under the direction of a physician, for the noninvasive intermittent measurement of fluid status in patients with end-stage kidney disease (ESKD) including those receiving maintenance dialysis.

The device does not generate any real-time alarms and outputs from the device should be used in the context of all clinical data to assess a patient's fluid status.

The device is intended for use in patients 18 years and older.

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.

1. 510(K) SUMMARY

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR § 807.92

1.1. Submitter's Information

Name:	Fresenius Medical Care Renal Therapies Group, LLC
Address:	920 Winter Street Waltham, MA 02451-1457
Phone:	(781) 996-9103
Contact Person:	Christopher Doherty, Regulatory Affairs Fellow
Phone:	(781) 296-4663
Preparation Date:	03 March 2025

1.2. Device Name

Trade Name:	BCM2 – Body Composition Monitor
Common Name:	Fluid Status Monitor
Regulation Name:	Impedance Plethysmograph
Regulatory Class:	Class II per 21 CFR § 870.2770
Product Code:	DSB
Product Code Name:	Plethysmograph, Impedance
FDA Review Panel:	Cardiovascular

1.3. Legally Marketed Predicate Device

1.3.1. Predicate Device – Intersection Medical Inc. IMED-Z (K142503)

The predicate device for the BCM2 - Body Composition Monitor (hereinafter referred to as the "BCM2") is the IMED-Z Fluid Status Monitor (K142503). The IMED-Z has not been the subject of a design-related recall.

1.3.2. Reference Device – Xitron Hydra 4000

The Xitron Hydra 4000 (K904109) is being used as a reference device to demonstrate the equivalence of technological characteristics (i.e., bioimpedance spectroscopy).

1.4. Device Description

The BCM2 is a multifrequency bioimpedance device that can be used by a clinician for the noninvasive intermittent measurement of fluid status in patients with end-stage kidney disease, including those receiving maintenance dialysis. A physician or designated healthcare professional is responsible for interpreting data from the device to determine what action is required as a result of changes in the measurements.

To assess a patient's hydration status, the BCM2 measures impedance by applying a low-level signal (50–800 µA) for less than 10 seconds at 50 different frequencies from 5 kHz to 1,000 kHz. Measurements are performed by dialysis clinicians (e.g., dialysis nurses, patient care technicians) in a healthcare environment such as a dialysis clinic or hospital.

In the normal clinical workflow, the BCM2 provides the following output parameters:

- Overhydration (OH)
- Urea distribution volume (V)

The following calculated and derived parameters are also available:

- Extracellular water (ECW)
- Intracellular water (ICW)
- Total body water (TBW)

The BCM2 system consists of the BCM2 touchscreen console and the electrode set. The BCM2 console powers and measures the bioimpedance spectroscopy frequencies to assess fluid parameters.

The device can also be operated in battery mode. Battery mode provides flexibility when moving between patients. The battery charge status is shown in the upper corner of the display regardless of which power source is being used. The power supply connection is located on the rear of the console.

The Calibration Box employs different resistors to calibrate the entire range of the BCM2's measurement (5 kHz to 1,000 kHz). Impedance measurements are performed for each resistor for all frequencies and the data is verified against an expected tolerance range. After the BCM2 has been calibrated, the Test Box is used to verify that the device is functioning properly.

The BCM2 will be available in one (1) configuration for sale within the U.S.

1.5. Intended Use

The BCM2 device provides objective intermittent measurement of parameters that assist the healthcare professional (HCP) in the assessment and monitoring of the patient's hydration and body composition.

In the normal clinical workflow, the device uses the following output parameters:

- Overhydration (OH)
- Urea distribution volume (V urea)

Other calculated and derived parameters are also made available.

The device will also display the Cole-Cole plot and the subject's weight, height, age, and sex.

1.6. Indications for Use

The BCM2 device is intended for use, under the direction of a physician, for the noninvasive intermittent measurement of fluid status in patients with end-stage kidney disease (ESKD) including those receiving maintenance dialysis.

The device does not generate any real-time alarms, and outputs from the device should be used in the context of all clinical data to assess a patient's fluid status.

The device is intended for use in patients 18 years and older.

1.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the BCM2 are substantially equivalent to the predicate device IMED-Z Fluid Status Monitor (K142503):

- Intended Use
- Indications for Use
- Fundamental Scientific Technology/Operating Principle
- Technological Characteristics

The following technological characteristic of the BCM2 is substantially equivalent to the predicate device Xitron Hydra 4000 (K904109):

- Bioimpedance Spectroscopy

1.8. Performance Data

The following performance tests were conducted on the BCM2 to support the determination of substantial equivalence:

- Software Verification and Validation
- Functional Design Verification
- Electrical Safety and Electromagnetic Compatibility (EMC)
- Simulated Shipping and Distribution
- Biological Safety (Biocompatibility)
  - Cytotoxicity
  - Sensitization
  - Irritation
  - Toxicological Review

All testing met predetermined acceptance criteria.

The BCM2's performance characteristics were demonstrated through bench testing, mechanical integrity testing, electrical safety and electromagnetic compatibility testing, and software testing.

Testing demonstrated that the integrity, durability, and reliability of the disposable electrodes were maintained over their intended shelf life.

The BCM2 is safe and effective for its intended use.

1.8.1. Biocompatibility Testing

In accordance with FDA guidance document *Use of International Standard ISO 10993, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* (September 4, 2020), the BCM2 electrodes are classified as a surface, intact skin, and limited exposure (≤ 24 hours) device.

The BCM2 electrodes were evaluated for biocompatibility in accordance with the requirements of:

- *ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
- *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* (September 4, 2020)

Based on the results of the biocompatibility tests performed on the BCM2 electrodes, FMCRTG has concluded that the electrodes are biologically safe for their intended use.

The following tests were performed to support the biological safety of the BCM2 electrodes (Table 1).

Table 1: Biocompatibility Performance Tests

Biological Safety Endpoint	Test	Acceptance Criteria	Standard	Result
Sensitization	ISO Closed-patch (Buehler) Test (GLP)	Non-Sensitizer Passes when numerical grade ≤ 1 (If grade ≤ 1 is observed for controls)	ISO 10993-10:2010 [Rec. Number 2-174]	Passed
Irritation	ISO Primary Irritation Study (Animal Irritation) (GLP)	Non-Irritant Passes when difference between test extract overall mean and corresponding control overall mean is ≤ 1		Passed
	ISO Primary Irritation Study (Animal Irritation) (GLP)	Non-Irritant Passes when difference between test extract overall mean and corresponding control overall mean is ≤ 1		Passed
	ISO Primary Irritation Study (Animal Irritation) (GLP)	Non-Irritant Passes when difference between test extract overall mean and corresponding control overall mean is ≤ 1		Passed

Biological Safety Endpoint	Test	Acceptance Criteria	Standard	Result
	ISO Primary Irritation Study (Animal Irritation) (GLP)	Non-Irritant Passes when difference between test extract overall mean and corresponding control overall mean is ≤ 1		Passed

1.8.1.1. *In Vitro* Cytotoxicity Testing

The electrode was cytotoxic in *in vitro* cytotoxicity testing.

Additional tests were conducted to fully characterize potential biocompatibility risk to the patient. These tests included the Animal Irritation Test and Closed Patch (Buehler) Test in accordance with ISO 10993-10, both of which had passing results with no response. As described in ISO 10993-5, a positive response does not necessarily indicate toxicity. This result shows that when the electrodes are used on intact skin in a live animal model there were no adverse responses.

1.8.2. Human Factors Validation Testing

The BCM2 was validated for its safe and effective use in accordance with FDA guidance document *Applying Human Factors and Usability Engineering to Medical Devices* (03 February 2016).

1.8.3. Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical Safety testing was conducted in accordance with *IEC 60601-1-2:2014*, and *IEC 60601-1-2:2014/AMD1:2020*. The BCM2 met acceptance criteria for this testing.

The BCM2 was evaluated for electromagnetic compatibility (EMC) in accordance with *IEC 60601-1-1:2005, IEC 60601-1:2005/AMD1:2012*, and *IEC 60601-1:2005/AMD2:2020*. The BCM2 met the EMC acceptance criteria.

1.8.4. Software Verification and Validation Testing

Unit, integration, regression (system verification), functional, and system testing were performed to demonstrate the effectiveness of the software and to confirm operation of the device. Software verification information within this submission is provided in accordance with the following:

- *Content of Premarket Submissions for Device Software Functions* (14 June 2023)
- *Off-The-Shelf Software Use in Medical Devices* (11 August 2023)
- *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions* (27 September 2023)
- *Select Updates for the Premarket Cybersecurity Guidance: Section 524B of the FD&C Act* (13 March 2024)
- *Applying Human Factors and Usability Engineering to Medical Devices* (3 February2016)

All testing met predetermined acceptance criteria.

The BCM2 is safe and effective for its intended use.

1.8.6 Animal Studies

No animal studies were performed for the BCM2.

1.8.7 Clinical Studies

A literature review was provided in support of the validation and accuracy of the BCM2 device, as well as clinical evidence for the determination of substantial equivalence, the proposed Indications for Use, and the Intended Use in the relevant patient populations.

1.9 Conclusion

The Indications for Use, design, principle of operation, and technological characteristics of the BCM2 and its components are substantially equivalent to those of the predicate and secondary predicate devices. Test results demonstrate that the differences between the BCM2, the predicate, and secondary predicate do not raise new concerns with regard to safety or efficacy. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, the BCM2 is safe and effective for its intended use.