July 29, 2022

Bodyport Inc.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K211585
Trade/Device Name: Bodyport Cardiac Scale
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II
Product Code: DSB
Dated: May 31, 2022
Received: June 1, 2022

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 (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/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.

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211585

Device Name
Bodyport Cardiac Scale

Indications for Use *(Describe)*
The Bodyport Cardiac Scale is intended for use, under the direction of a physician, for the non-invasive monitoring and management of patients with fluid management related health conditions. The device is intended to be used to measure and track body weight, peripheral impedance, pulse rate, and center of pressure. The device is intended to be used in the home or clinic environment.

Intended users are people over 21 years of age who can stand for the duration of the measurement and weigh less than 180 kg (397 lbs).

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 status.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

(5) 510(k) Summary

510(k) Owner/ Submitter:	Bodyport Inc. 970 Folsom Street San Francisco, California 94107 (USA) P: (650) 200-1557
Contact Person:	Corey Centen P: (415) 990-5415 E: corey@bodyport.com
Date Prepared:	July 21, 2022
Trade Name:	Bodyport Cardiac Scale (or Bodyport Scale)
Device Type/ Common Name:	Plethysmograph, Impedance
Classification Name:	Impedance plethysmograph
Classification Regulation:	870.2770
Class:	II
Panel:	Cardiovascular
Product Code:	DSB
Predicate Device(s):	Noninvasive Medical Technologies, Inc.'s ZOE Fluid Status Monitor Model ZOE3 (K133301)
Reference Device(s):	N.I. Medical, Ltd.'s NICaS 2001 Noninvasive Cardio-Respiratory System (K942227) ImpediMed Limited's SOZO (K172507)

Device Description:

The Bodyport Cardiac Scale is a non-invasive cardiovascular monitor and body weight scale that measures body weight, peripheral impedance, pulse rate, and center of pressure through the feet of a user standing on its surface. The device is powered by four (4) AA alkaline batteries.

The device is comprised of a physical platform on which the user stands with bare feet. Four electrodes located on the top surface of the platform are used to measure the impedance of the user's lower body (foot-to-foot). The impedance signal is obtained by applying a small, safe battery-generated current (<500uA) between the feet of the user and measuring the resulting electrical potential. The impedance signal reflects the electrical resistance of the lower body and is modulated by changes in fluid levels and blood flow in the lower part of the body, enabling the calculation of parameters such as pulse rate and

peripheral impedance. The impedance signal is captured at two frequencies (8kHz and 64kHz) to enable the calculation of peripheral impedance values that reflect intra- and extra-cellular fluid levels. The 64kHz signal is used to calculate impedance magnitude and phase angle to measure pulse rate.

Additionally, load cells in each of the four corners of the device measure the static and dynamic loads being applied to the device by the user's body. The load cells are used to measure the user's body weight and center of pressure. The device may show body weight, peripheral impedance, and pulse rate information on a display integrated into the platform.

A user is instructed to stand on the Bodyport Cardiac Scale with bare feet. The measurement starts automatically when the user steps on the scale. The device acquires the data and notifies the user that the measurement is complete through a gentle haptic vibration and displays the results on the device screen. Data collected by the Bodyport Cardiac Scale is automatically transmitted via cellular communication to the Bodyport cloud where it can be accessed through a supported web-based browser, dashboard or API.

Intended Use/ Indications for Use:

The Bodyport Cardiac Scale has the same intended use as the predicate device; it raises neither new nor different questions of safety and effectiveness compared to the predicate device.

Indications for Use:

The Bodyport Cardiac Scale is intended for use, under the direction of a physician, for the non-invasive monitoring and management of patients with fluid management related health conditions. The device is intended to be used to measure and track body weight, peripheral impedance, pulse rate, and center of pressure. The device is intended to be used in the home or clinic environment.

Intended users are people over 21 years of age who can stand for the duration of the measurement and weigh less than 180 kg (397 lbs).

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 status.

Technological Characteristics:

The Bodyport Cardiac Scale has the same or similar technological characteristics – materials, design, and energy source – as the predicate device; it raises neither new nor different questions of safety and effectiveness compared to the predicate device.

A summary table is included for reference:

Predicate Device Comparison			
Description:	**Predicate Device – ZOE Fluid Status Monitor Model ZOE3**	**Subject Device – Bodyport Cardiac Scale**	**Discussion of Differences**
Device Name:	ZOE Fluid Status Monitor Model ZOE3	Bodyport Cardiac Scale	N/A
510(k) Number:	K133301	-	N/A
Device Classification and Product Code:	Class II/DSB	Class II/DSB	No differences
Prescription Device:	Yes	Yes	No differences
Device Description:	The ZOE Fluid Status Monitor Model ZOE3 is a non-invasive, battery powered impedance monitor designed as an 'early warning' monitor for determining changes in the fluid status of patients with fluid management problems. The ZOE Fluid Status Monitor Model ZOE3 works by applying a low amplitude high frequency electrical current to the body and measuring the electrical impedance. Base Impedance also known as Z_0, decreases when fluid increases and increases when fluid decreases. The ZOE Fluid Status Monitor Model ZOE3 is designed for use with disposable, self-adhesive silver/ silver chloride electrodes that are readily available from Noninvasive Medical Technologies, Inc. NMT approved electrodes must be used with the ZOE Fluid Status Monitor. Z_0 readings obtained from unapproved electrodes may not be accurate!	The Bodyport Cardiac Scale is a non-invasive cardiovascular monitor and body weight scale that measures body weight, peripheral impedance, pulse rate, and center of pressure through the feet of a user standing on its surface. The device is powered by four (4) AA alkaline batteries. The device is comprised of a physical platform on which the user stands with bare feet. Four electrodes located on the top surface of the platform are used to measure the impedance of the user's lower body (foot-to-foot). The impedance signal is obtained by applying a small, safe battery-generated current (<500uA) between the feet of the user and measuring the resulting electrical potential. The impedance signal reflects the electrical resistance of the lower body and is modulated by changes in fluid levels and blood flow in the lower part of the body, enabling the calculation of parameters such as pulse rate and peripheral impedance. The impedance signal is captured at two frequencies (8kHz and 64kHz) to enable the calculation of peripheral impedance values that reflect intra- and extra-cellular fluid levels. The 64kHz signal is used to calculate impedance magnitude and phase angle to measure pulse rate. Additionally, load cells in each of the four corners of the device measure the static and dynamic loads being applied to the device by the user's body. The load cells are used to measure the user's body weight and center of pressure. The device may show body weight, peripheral impedance, and pulse rate information on a display integrated into the platform. A user is instructed to stand on the Bodyport Cardiac Scale with bare feet. The measurement starts automatically when the user steps on the scale. The device acquires	The Bodyport Cardiac Scale measures body weight, peripheral impedance, pulse rate, and center of pressure, and has cellular connectivity.

		the data and notifies the user that the measurement is complete through a gentle haptic vibration and displays the results on the device screen. Data collected by the Bodyport Cardiac Scale is automatically transmitted via cellular communication to the Bodyport cloud where it can be accessed through a supported web-based browser, dashboard or API.	
Indications for Use:	The ZOE 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.	The Bodyport Cardiac Scale is intended for use, under the direction of a physician, for the non-invasive monitoring and management of patients with fluid management related health conditions. The device is intended to be used to measure and track body weight, peripheral impedance, pulse rate, and center of pressure. The device is intended to be used in the home or clinic environment. Intended users are people over 21 years of age who can stand for the duration of the measurement and weigh less than 180 kg (397 lbs). 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 status.	No clinical differences: The Bodyport Cardiac Scale measures impedance, the same as the predicate device. Additionally, the Bodyport Cardiac Scale measures pulse rate, weight, and center of pressure. Pulse rate is measured from the same impedance signal used to measure peripheral impedance. Stand-on patient scales – product code FRI – are 510(k) exempted devices per regulation number 880.2700, as are force-measuring platforms – product code KHX – per FDA regulations number 890.1575. These additional metrics provide clinicians greater context when interpretating changes in the fluid status of patients, without altering standard of care. These features are therefore not critical to the intended use of the device and do not affect its safety and effectiveness.
Technical Method:	2.0mA current at 100kHz	<500 µA current at 8kHz and 64kHz	No functional differences: The Bodyport Cardiac Scale performs in the same manner with lower applied currents, modulated at two frequencies instead of one. The differences in frequency have minimal impact on measurement accuracy. The use of two frequencies enables calculation of impedance values that represent extra- and intra-cellular fluid levels. This does not raise new

			questions of safety and effectiveness.
Operating Principle:	A small current of 2.0mA is applied across the chest of the patient to measure impedance. The current is modulated at 100kHz.	A small, battery-generated current of <500uA is applied to the feet of the patient to measure impedance. The current is modulated at two frequencies, 8kHz and 64kHz.	No functional differences: The Bodyport Cardiac Scale performs in the same manner – through the lower body versus across the chest – with lower applied current, modulated at two frequencies.
Electrode Configuration:	Tetrapolar; wet electrodes	Tetrapolar; dry electrodes	No functional differences: The current source design and electrode configuration enable the use of dry electrodes with minimal impact on measurement accuracy.
Impedance Measurement Range:	15-45 ohms	150-1250 ohms	No functional differences: The ranges vary due to use of different segments of the body.
Connectivity:	None	Cellular (LTE-M)	The Bodyport Cardiac Scale has cellular connectivity for longitudinal data collection and review.
Display:	7-segment LCD display	White LED display: 43 x 17 pixels	No functional differences: The Bodyport Cardiac Scale uses an LED-matrix display integrated into the device.
Measurement Time:	30 seconds	30 seconds	No differences
Batteries and Power:	Four (4) AA alkaline batteries, user replaceable, or 5V DC Power adapter (GTM31060-1505)	Four (4) AA Alkaline, user replaceable	No functional differences: The Bodyport Cardiac Scale does not use a DC power adapter.
Performance Data/ Standards:	CAN/CSA 22.2 No 60601-1:08 60601-1, 3rd Edition 60601-1-2	ISO 10993-1:2018 IEC 60601-1:2005, A1:2012 IEC 60601-1-2:2014 IEC 60601-1-6:2010+A1:2013 IEC 62366-1:2015 IEC 60601-1-11:2015 ASTM D4169-16 ASTM D4332-14 IEC 62304:2006+A1:2015	No functional differences: The Bodyport Cardiac Scale has undergone additional testing.

Non-Clinical Performance Data:

Biocompatibility Testing:

A biocompatibility evaluation for the Bodyport Cardiac Scale – considered tissue contacting for a duration of less than 24 hours – was conducted and documentation 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 4, 2020 and International Standard ISO 10993-1:2018, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", as recognized by FDA. The battery of testing included:

- Cytotoxicity
- Sensitization
- Irritation

Electrical Safety and Electromagnetic Compatibility (EMC) Testing:

Electrical safety and electromagnetic compatibility (EMC) testing were conducted on the Bodyport Cardiac Scale. The device complies with IEC 60601-1:2005, A1:2012, "Medical electrical equipment – Part 1: General requirements for basic safety and essential performance" and its relevant collateral standards, including IEC 60601-1-11:2015, "Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment" and IEC 60601-1-2:2014, "Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests", as recognized by FDA.

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

As a device that operates on the licensed radio spectrum, Bodyport conducted PTCRB testing to ensure proper LTE-M transmission reliability.

Software Verification and Validation Testing:

The Bodyport Cardiac Scale complies with IEC 62304:2006+AMD1:2015 CSV, "Medical device software – Software life cycle processes", as recognized by FDA.

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", May 11, 2005. The software for this device was considered as a "moderate" level of concern since a failure or latent flaw in the software could directly result in minor injury to the patient.

Human Factors Validation Testing:

The Bodyport Cardiac Scale complies with IEC 60601-1-6:2010+A1:2013, "Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability"/ IEC 62366-1:2015, "Medical devices – Part 1: Application of usability engineering to medical devices", as recognized by FDA.

Additionally, human factors and usability engineering testing for the Bodyport Cardiac Scale was conducted and documentation was 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:

Measurement accuracy and linearity of the Bodyport Cardiac Scale were compared to the predicate device to determine substantial equivalence**.**

Implantable Electronic Cardiac Device (IECD) Compatibility Testing:

Bench testing of the Bodyport Cardiac Scale with implantable electronic cardiac devices was performed using the torso simulator described in ANSI/AAMI/ISO 14117:2012 EMC Test Protocol and IECD test specimens.

Clinical Data:

Pulse Rate:

Clinical testing demonstrated the accuracy of the pulse rate measurement from the Bodyport Cardiac Scale compared to a reference single lead ECG heart rate measurement. For this study, adult subjects, with a range of peripheral impedances and pulse rates, were analyzed.

Peripheral Impedance:

Analysis of clinical data demonstrated the clinical utility of peripheral impedance in the monitoring of patients with fluid management conditions. This analysis included clinical data from patients with heart failure, as an example patient population with fluid management related health conditions, and healthy subjects, as a control population.

Additional testing demonstrated the correlation between impedances measured through hand-to-foot and foot-to-foot body segments. For this study, adult subjects, with a range of peripheral impedances, were analyzed.

Conclusions:

The non-clinical and clinical data support the safety of the Bodyport Cardiac Scale and the hardware and software verification and validation demonstrate that the device should perform as intended in the specified use conditions.

The Bodyport Cardiac Scale is substantially equivalent to the predicate device.