June 25, 2026

Intelligent Dots LLC.
% Boyle Wang
General Manager
Abmed Medical Technology Inc.
800 East Wishkah Street, Suite 1021
Aberdeen, Washington 98520

Re: K253274
Trade/Device Name: BedDot (G1)
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: BZQ
Dated: May 18, 2026
Received: May 18, 2026

Dear Boyle Wang:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

PRAKHYAT SINGH -S

Digitally signed by PRAKHYAT SINGH -S
Date: 2026.06.25 14:55:14 -04'00'

For
Rachana Visaria
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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.

510(k) Number *(if known)*
K253274

Device Name
BedDot (G1)

Indications for Use *(Describe)*
BedDot (G1) is a non-contact, bed-mounted vital signs monitor intended to provide continuous measurement of respiratory rate (RR) within a validated operating range of 12–24 breaths/min, and movement in adult patients lying in a supine, resting position in a hospital ward or clinic setting. The operation of the BedDot (G1) has been studied in adults (weight ≥ 50Kg and weight ≤115Kg) during sleep and resting condition.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
K253274

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's Information

Name: Intelligent Dots LLC.
Address: 147 Technology Pkwy, Peachtree Corners Norcross, GA 30092.
Tel: (470) 647-8588
Contact: Dr. WenZhan Song
Email: info@intelligentdots.com

Designated Submission Correspondent

Contact: Mr. Boyle Wang
Name: Abmed Medical Technology Inc.
Address: 800 East Wishkah Street, Suite 1021 Aberdeen, WA98520
Tel: 303-8000162
Email: info@abmed.us

Date of Preparation: June 25,2026

2.0 Device Information

Trade name: BedDot (G1)
Common name: Monitor, breathing frequency
Classification name: Breathing frequency monitor
Model(s): G1
Production code: BZQ
Regulation number: 21 CFR 868.2375
Classification: Class II
Panel: Anesthesiology

3.0 Predicate&Reference Device Information

Primary Predicate#

Manufacturer: EarlySense Ltd.
Trade name: EarlySense InSight System
510(k) number: K152911

4.0 Indication for Use Statement

BedDot (G1) is a non-contact, bed-mounted vital signs monitor intended to provide continuous measurement of respiratory rate (RR) within a validated operating range of 12–24 breaths/min, and movement in adult patients lying in a supine, resting position in a hospital ward or clinic setting. The operation of the BedDot (G1) has been studied in adults (weight ≥ 50Kg and weight ≤115Kg) during sleep and resting conditions.

5.0 Device Description

The BedDot (G1) (hereinafter referred to as the test device or BedDot) is a non-contact bed occupancy and vital signs monitor based on a vibration sensing technology using seismic sensors that detect very small vibrations. When installed under a bed, the BedDot can be used to continuously measure the respiration rate (RR) of adult patients lying in a resting position. The system also provides information on bed occupancy and body movements.
The BedDot is intended for use by clinicians or other trained medical personnel under still conditions only. It is not indicated for active patient monitoring, does not provide alarms for timely response in life-threatening situations, and is not intended for use in patients with arrhythmias.
The BedDot system consists of the main unit and compatible accessories, including a power adapter, USB-C cable, and adhesive metal plate for mounting. The main unit incorporates a vertical geophone sensor module, an analog-to-digital converter (ADC) board, and an embedded computing module. The geophone contains a magnetic element suspended within a coil assembly; micro-vibrations induced by physiological activity cause relative motion between the magnet and coils, generating an electrical signal. The ADC digitizes the signal at 100 Hz for subsequent processing by the embedded computing module.

The following parameters are estimated:
- Respiratory Rate;
- Bed Occupancy;
- Body Movements.

The BedDot operates in a direct device-to-server configuration. Each BedDot device integrates micro-vibration sensing technology and includes a built-in Wi-Fi module for secure data transmission to a designated backend application hosted on a server.The backend application processes incoming sensor data to derive respiratory rate (RR), bed occupancy status, and body movement parameters. Processed information is presented through a secure web-based user interface that allows authorized users to review current parameter status and historical trend data.

The device is non-sterile, reusable, and contains no patient-contacting components.

6.0 Technological Characteristic Comparison Table

Parameter	BedDot (G1) (K253274)	EarlySense InSight System (K152911)	Substantial Equivalence
Product Code	BZQ	BZQ	Same
Regulation Number	868.2375	868.2375	Same
Classification Name	Breathing Frequency Monitor	Breathing Frequency Monitor	Same
Manufacturer	Intelligent Dots, Inc.	EarlySense Ltd.	--
Intended Use	BedDot (G1) is a non-contact, bed-mounted vital signs monitor intended to provide continuous measurement of respiratory rate (RR) within a validated operating range of 12–24 breaths/min, and movement in adult patients lying in a supine, resting position in a hospital ward or clinic setting. The operation of the BedDot (G1) has been studied in adults (weight ≥ 50Kg and weight ≤115Kg) during sleep and resting conditions.	The EarlySense InSight system is intended for continuous measurement of respiration rate, heart rate and movement, in an automatic contact less manner, in hospital or clinic setting. The system is indicated for use in children, adolescents and adults. The operation of the EarlySense has been studied in children (weight ≥ 10 Kg) and adults (weight <111 Kg) during sleep and resting condition.	Similar, general intended use with respiratory rate (RR)-only functionality and narrower adult-only patient population.
Sensing Unit	Seismic Sensor (under mattress)	Piezoelectric sensor (under mattress/chair)	Similar, both technologies are passive, sensing methods that detect mechanical vibrations generated by patient physiological activity without direct patient contact and therefore does not raise different questions of safety or effectiveness
Signals acquired	Vibration signal generated by chest movement (respiration), and body movements.	Piezoelectric signal generated by variations of pressure applied on the device due to body motion, chest movement (respiration), and vibrations created by the heart.	Similar, both devices acquire vibrations associated with respiration and body movement and process these signals to derive the

			same physiological information.
SpO2 Module	Not supported	Not supported	Same
Bedside Unit	Processing unit; no display	Processing unit; no display	Same
Energy Source	+5VDC Micro C connector supplied by AC power module	AC power	Different Does not raise new questions of safety or effectiveness and is addressed through electrical safety and power reliability testing
Clinical Environment	Hospital or clinic	Hospital or clinic	Same
Patient Population	Adults	Children, adolescents, adults	Different, Narrower intended population
Bedside Visual/Audio	No bedside clinical alarm; Device status indicators only	LEDs and buzzer	Different, the absence of alarm functionality in the subject device represents a narrower intended functionality and does not adversely affect the device's ability to perform its intended monitoring functions.
User Interface Display at Bedside	None	None	Same
Network Communication	LAN / Wi-Fi	LAN / Wi-Fi	Same
Monitoring Parameters	RR, Movement, Bed Occupancy	HR, RR, Movement, Bed/Chair Occupancy	Similar, the differences represent a narrower monitoring scope for the subject device and do not alter the safety and

			effectiveness of the device.
Visual Status Indication	RR(Range: 12-24 bpm) Motion, Bed Occupancy	HR(Range: 30 - 170bpm RR(6-45 bpm) Motion, Bed/Chair Occupancy	Similar, difference represents a narrower set of displayed physiological parameters and does not affect the device's ability to perform its intended respiratory monitoring, occupancy detection, and movement monitoring functions.
Accuracy	MAE of 1.77 breaths/min, and RMSE of 2.80 breaths/min based on clinical study results	Not publicly Available	The subject device's RR accuracy is supported by clinical validation testing against a manually reviewed $etCO_2$ reference methodology.
Displayed Information	Displayed remotely via central station	Displayed remotely via central station	Same

Substantial Equivalence Summary:

The subject device, BedDot (G1), and the predicate device, EarlySense InSight System (K152911), have substantially equivalent intended use in that both are non-contact monitoring systems intended to provide physiological information, including respiratory rate (RR), movement, and occupancy-related status, for review by healthcare professionals in clinical care environments. Both devices utilize contact-free sensing technologies positioned beneath the patient support surface to detect low-amplitude mechanical signals associated with physiological activity. The predicate device uses a piezoelectric sensing element embedded in a bed sensor panel, while the subject device uses a geophone-based vibration sensing element installed under the bed frame. Despite this difference in sensing hardware, both devices employ the same fundamental measurement approach: acquisition of mechanical micro-motion signals generated by cardiac activity, respiration, and body movement, followed by signal processing to derive clinically relevant physiological parameters.

7.0 Non-clinical Testing Summary

The following performance data have been conducted to verify that the BedDot meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate device. The testing results demonstrate that the targeted device complies with the following standards:

Electrical & EMC Safety and Wireless:

The electrical safety and EMC safety testing was performed to, and passed, the following standards:

- IEC 60601-1:2005/AMD2:2020, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2:2020, Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral standard: Electromagnetic disturbances - Requirements and tests
- IEC TS 60601-4-2:2024, Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 62133-2:2021, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
- USEMCSC C63.27-2021, American National Standard for Evaluation of Wireless Coexistence
- Electromagnetic Compatibility (EMC) of Medical Devices Guidance Document (June 2022)
- NSI C63.27-2021, American National Standard for Evaluation of Wireless Coexistence
- AAMI TIR69:2017 (R2020) Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems
- Radio Frequency Wireless Technology in Medical Devices – Guidance for Industry and Food and Drug Administration Staff (August 2020)

Risk Analysis

Risk Analysis was performed on the subject device as recommended by

ISO 14971:2019, Medical devices - Application of risk management to medical devices and risk controls were implemented to mitigate all identified hazards through suitable modifications to each components' functionality, labeling and packaging, IFU and User Manual. All foreseeable cybersecurity risks associated with the subject device have been identified in addition to finding timely errors through penetration testing.

Summary of Bench Testing

Bench testing included continuous operation, repeated use, drift and durability stability, long-term stability under accelerated aging, environmental interference, temperature variation, motion detection sensitivity, occupancy detection, and drop/mechanical robustness was conducted and the results show that the subject device complies with applicable performance criteria.

Software Verification and Validation Testing

Software documentation including verification & validation was provided in accordance with FDA Guidance "Content of Premarket Submissions for Device Software Functions". The Software Validation is in compliance with FDA Guidance (June 2023).

Cybersecurity

Cybersecurity risk assessment and controls of the Device was carried out per the FDA guidance, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance for Industry and Food and Drug Administration Staff (February 2026)"

Shelf-life & Reliability

Shelf-life & Reliability and testing were conducted and verified on the BedDot.

Cleaning

Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance (March 2015)

Biocompatibility Testing

As BedDot (G1) is a contactless device, this testing is not applicable for the subject device.

8.0 Clinical Test Summary

A clinical validation study was conducted to evaluate the accuracy of the BedDot (G1) system for measuring respiration rate (RR) in adult subjects under the device's intended use conditions (resting/supine, still conditions in a healthcare facility setting). A total of 52 adult subjects from the intended population were enrolled and analyzed at the Clinical and Translational Research Unit, University of Georgia, USA.

For respiration rate validation, BedDot RR outputs were evaluated against clinician-manually scored respiratory rates derived from the raw etCO_2 capnography waveform using the FDA-cleared Mindray BeneVision N17 (K202405). Two independent blinded clinicians manually counted respiratory cycles from the raw waveform, with adjudication by a third blinded clinician when needed. The primary RR validation was restricted to the intended operating range of 12–24 breaths/min, consistent with the device's intended use population. BedDot achieved an RR MAE of 1.77 breaths/min, and RMSE of 2.80 breaths/min, and STD of 2.57 breaths/min.

Demographic subgroup analyses (sex, age, BMI) and time-range analyses demonstrated consistent performance within the evaluated intended-use population. No device-related adverse events, serious adverse events, or device stability issues were observed during the study.

The clinical test results support clinically acceptable accuracy of BedDot for RR within the intended-use environment.

9.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the subject device is substantially equivalent to the legally marketed predicate device.