September 26, 2024

BioIntelliSense Inc.
Yusi Liu
Senior Vice President, Regulatory Affairs and Quality Assurance
570 El Camino Real,
Suite 200
Redwood City, California 94063

Re: K241101
Trade/Device Name: BioButton System
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG
Dated: August 28, 2024
Received: August 28, 2024

Dear Yusi Liu:

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,

Jennifer W. Shih -S

Jennifer Kozen
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241101

Device Name

BioButton System

Indications for Use *(Describe)*

The BioButton System is a remote monitoring wearable device intended for continuous collection of physiological data in home and healthcare settings while the patient is at rest. This could include heart rate, respiratory rate, skin temperature, and other data such as activity level, body position, sleep, and step and gait analysis.
Data are securely transmitted via wireless connection for storage, review, analysis, and display.
The Device can include the ability to display data and notify healthcare professionals when physiological data fall outside clinician-specified parameters.
The data from the Device are intended as an aid to diagnosis, disease management, and treatment.
The Device is intended for use on patients who are 18 years of age or older.
The Device is not intended to output physiological measurements while the patient undergoes significant motion or is active.
The Device is not intended for critical care.

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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"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."

510k Summary for

BioButton System

Overview

This summary of 510(k) substantial equivalence (SE) information can be found in sections below in accordance with the requirements of 21 CFR §807.92.

This document applies to the submission of the BioButton System.

I. Submitter

Submitter Name and Address	BioIntelliSense Inc. 570 El Camino Real, #200 Redwood City CA 94063 USA
Contact Person	Yusi Liu – VP of Regulatory Affairs Tel: +1 703-776-0119 Email: yliu@biointellisense.com

II. Device

Name of Device	BioButton System
Regulation Name	Radiofrequency Physiological Signal Transmitter and Receiver
Regulation Number	21 CFR 870.2910
Regulatory Class	Class II
Product Code(s)	DRG

III. Predicate Device

Predicate Device Manufacturer	BioIntelliSense Inc.
Predicate Device Trade Name	BioButton System
Predicate Device 510(k) Number	K212957

III.A. Reference Device

Reference Device Manufacturer	Reference Device Name	Reference Device 510(k) Number
Vios Medical, Inc.	Vios Monitoring System™ Model 2050	K172586
Vivify Health, Inc.	Vivify Health Inc. Care Team Portal	K222398

IV. Device Description

The BioButton System (the "Device") is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings while the patient is at rest. This can include heart rate, respiratory rate, and skin temperature. Data are transmitted from the Device for storage and analysis.

The Device is an extension of the Predicate Device (K212957) with the same intended use. The Device consists of a multiple-use and rechargeable wearable hardware sensor module to collect data from a patient and other Medical Device Data System (MDDS) components that enables remote transfer of collected data. The main components of the Device include the following:

1. A wearable sensor to collect data from a patient
2. A device-based Medical Device Data System (MDDS) data gateway to transfer data from the wearable sensor to the cloud
3. A cloud-based Medical Device Data System (MDDS) for data storage and transmission
4. A cloud-based system for configuration of the wearable sensor and data analysis
5. A cloud-based system for healthcare professionals to view patient information

The Device is used to collect physiological information from a patient using the sensor for a set duration (as defined by different use cases) in home and healthcare settings. Physiological data is collected continuously while the patient is at rest[1]. The medical physiological data collected includes:

- Heart rate at rest,

[1] "At Rest" means the device will not output measurement data to the user or clinician while the user undergoes significant motion or is active.

- Respiratory rate at rest, and
- Skin temperature

There are other wellness parameters that can be collected by the device that include: activity level, body position, sleep, and step and gait analysis. These wellness data types are not discussed in detail the regulatory submission since they do not meet the definition of medical device.

Upon completion of a physiological data collection period, the data offload is conducted via wireless Bluetooth connection using the Offload Software. The data offloading is performed by trained and qualified personnel. The Device also provides a web display for healthcare professionals to view patient information.

V. Intended Use and Indications for Use

The BioButton System is a remote monitoring wearable device intended for continuous collection of physiological data in home and healthcare settings while the patient is at rest. This could include heart rate, respiratory rate, skin temperature, and other data such as activity level, body position, sleep, and step and gait analysis.

Data are securely transmitted via wireless connection from the device for storage, review, analysis, and display.

The Device can include the ability to display date and notify healthcare professionals when physiological data fall outside clinician-specified parameters.

The data from the device are intended as an aid to diagnosis, diseases management, and treatment.

The device is intended for use on users who are 18 years of age or older.

The device is not intended to output physiological measurements while the user undergoes significant motion or is active.

The device is not intended for critical care.

VI. Technology Characteristics in Comparison with the

Comparison Items	BioButton System (The Subject Device)	The Predicate Device (K212957)	Justification of Difference
Product Code	DRG	DRG	Same
Classification	Class II	Class II	Same
Intended use	The BioButton System (“the Device”) is a remote monitoring wearable device intended for continuous collection of	The BioButton System is a remote monitoring wearable device intended for continuous collection of physiological data	Same

Comparison Items	BioButton System (The Subject Device)	The Predicate Device (K212957)	Justification of Difference
	physiological data in home and healthcare settings while the patient is at rest. This could include heart rate, respiratory rate, skin temperature, and other data such as activity level, body position, sleep, and step and gait analysis. Data are securely transmitted via wireless connection for storage, review, and further analysis. The data from the Device are intended as an aid to diagnosis, disease management, and treatment. The Device is intended for use on patients who are 18 years of age or older. The Device is not intended to output physiological measurements while the patient undergoes significant motion or is active. The Device is not intended for critical care.	in home and healthcare settings while the patient is at rest. This could include heart rate, respiratory rate, skin temperature, and other symptomatic or biometric data. Data are securely transmitted via wireless connection from the device for storage, review, and further analysis. The data from the device are intended as an aid to diagnosis, diseases management, and treatment. The device is intended for use on users who are 18 years of age or older. The device is not intended to output physiological measurements while the user undergoes significant motion or is active. The device is not intended for critical care.	
Prescription Use / OCT	Prescription use only	Prescription use only	Same
Mode of Operation	Continuous operation	Continuous operation	Same
Physical Dimension	42.4x40.0x8.5mm	41.2x37.5x5.7mm	Similar
Weight	11.6g	9.4g	Similar
Patient Population	General care patients who are 18 years of age or older	General care patients who are 18 years of age or older	Same
Use Environment	Home and healthcare setting	Home and healthcare setting	Same
Device Placement	Upper left chest	Upper left chest	Same
Usability	Single button on device. Single LED indicator.	Single button on device. Single LED indicator.	Same
Operating Temperature	0°C - 40 C°	0°C - 40 C°	Same

Comparison Items	BioButton System (The Subject Device)	The Predicate Device (K212957)	Justification of Difference
Operating Relative Humidity (RH)	10-95% RH	10-95% RH	Same
Operating atmosphere pressure	70 kPa to 102 kPa	70 kPa to 102 kPa	Same
Transport & Storage Temperature	10 C°- 35C°	-20 C°- 40 C°	Equivalent
Transport & Storage Humidity	10 – 75% RH	10 – 95% RH	Equivalent
Single-use / Multiple-use	Multiple-use	Single-use	Different
Sterilization	No	No	Same
Re-processing between each use?	No	No	Same
Biologics or drugs?	No	No	Same
Data Display and Notifications	Through software portal included in Device	Through 3rd party portals (such as EMR)	Different

Technical Specifications

Comparison Items	BioButton System (The Subject Device)	The Predicate Device (K212957)	Justification of Difference
Battery Operated	Yes	Yes	Same
Sensor for Axillary Temp	Thermistor	Thermistor	Same
Sensor for Heart Rate	Accelerometer	Accelerometer	Same
Sensor for Respiratory Rate	Accelerometer	Accelerometer	Same
Data Storage - media	Flash storage	Flash storage	Same
Data Transfer	Wireless - Bluetooth	Wireless - Bluetooth	Same
On-device Controls	Physical push button	Physical push button	Same

Safety

Comparison Items	BioButton System (The Subject Device)	The Predicate Device (K212957)	Justification of Difference
General electrical and mechanical safety	Complies with IEC 60601-1 and EC 60601-1-11	Complies with IEC 60601-1 and EC 60601-1-11	Same
EMC	Complies with IEC 60601-1-2	Complies with IEC 60601-1-2	Same
Biocompatibility for Patient-contacting materials	Complies with ISO 10993-1 and collateral standards, as well as FDA guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*	Complies with ISO 10993-1 and collateral standards, as well as FDA guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*	Same
Ingress Protection	IP47	IP47	Same
On-device or Software Warning and Indication Signals	On-device LED indicator for power	On-device LED indicator for power	Same

Performance

Comparison Items	BioButton System (New Submission)	BioSticker System (K191614)	Justification of Difference
Heart Rate Range	40-150 Beats per Minute	40-125 Beats per Minute	Similar
Heart Rate Accuracy	5 Beats per minute (<±5 Beats per minute)	5 Beats per minute (<±5 Beats per minute)	Same
Respiratory Rate Range	5-35 Breaths per Minute	10-30 Breaths per Minute	Similar
Respiratory Rate Accuracy	3 Breaths per Minute (<±3 Breaths per Minute) at rest	3 Breaths per Minute (<±3 Breaths per Minute) at rest	Same
Skin Temperature	Meets ASTM E1112-00 standard Range 86°F - 107°F (30°C - 42°C)	Meets ASTM E1112-00 standard Range 86°F - 107°F (30°C - 42°C)	Same

VI. Performance Testing

Verification and validation activities established the safety and performance characteristics of the proposed device with respect to the predicate. The following performance data have been provided in support of the substantial equivalence determination:

Electrical safety and electromagnetic compatibility (EMC)	Electrical safety and EMC testing were conducted on the Device. The Device complies with the IEC 60601-1, IEC 60601-1-2, and IEC 60601-1-11 standards.
Software Verification and Validation Testing	The software for the Device is determined as a "Basic" documentation level per FDA Guidance Document < Content of Premarket Submissions for Device Software Functions – Guidance for Industry and Food and Drug Administration Staff > Software documentation and verification are performed per the guidance document.
Biocompatibility	Complies with ISO 10993-1 and collateral standards, as well as FDA guidance document < Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" – Guidance for Industry and Food and Drug Administration Staff > All skin-contacting materials meet or exceed the biocompatibility requirements, per testing against ISO 10993-5 and ISO 10993-10 standards.
Benchtop Testing	• Wireless coexistence testing conducted on the Device • Temperature measurement performance validation per ASTM E1112 standard per the Device's measurement range • Electronics hardware verification and validation testing - Testing shows that the electronics hardware of the Device functions as intended • Battery life testing - Testing verifies the battery life of the Device • Cleaning validation – testing validates cleaning and disinfection instructions for multiple-patient use
Animal Study	No animal / pre-clinical study was conducted.
Clinical Studies	Clinical studies were performed on the general population to confirm the measurement performance for heart rate and respiratory rate. The device is tested on general adult patient population. The study population consisted of 52 qualified subjects. 1394 datasets were collected for heart rate and 1898 datasets were collected for respiratory rate. Subjects race/ethnicity subgroups information is as follows: white: 10 (~20.0%); Hispanic or Latino: 13 (~25.0%); Black or African American: 6 (~11.5%); Asian: 19 (~36.5%); and Others: 4 (~7.7%). Subjects gender subgroups information is as follows: Male: 25 (~48.1%); and Female: 27 (51.2%). Subject age subgroups information is as follows: 21-29 years: 6 (~11.5%); 30-39 years: 13 (~25.0%); 40-49 years: 10 (~19.2%); 50-59 years: 5 (~9.6%); 60-69 years: 12 (~23.1%); 70-79 years: 6 (~11.5%); and 80 or above: 0 (0%). Subjects Body Mass Index (BMI) subgroups information is as follows: Normal (BMI less than 24.9): 17 (~32.7%); Overweight (BMI 25 -29.9): 18 (~34.6%); and Obese (BMI 30 or above): 17 (~32.7%) . In summary, all subgroups independently met device accuracy claims for heart rate and respiratory rate measurements. There is no known clinically meaningful subgroup disparities between race/ethnicity, gender, age, or BMI subgroups regarding device performance.

Human Factor	Human factor engineering and evaluation for Device was conducted per FDA guidance document < Applying Human Factors and Usability Engineering to Medical Devices - Guidance for Industry and Food and Drug Administration Staff>. Human factor study was conducted to ensure lay person could use the Device correctly with no human factor concerns.
Cybersecurity	Cybersecurity risk assessment and controls of the Device was carried out per the FDA guidance document < Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions – Guidance for Industry and Food and Drug Administration Staff >

VII. Conclusions

There are many similarities between the devices in comparison regarding intended use, technology, and most of the indications for use. The minor differences between the Device and the Predicate Device (K212957) do not raise new concerns. Thus, the Device, BioButton System and the Predicate Device (K212957) are substantially equivalent.