December 12, 2022

BiolntelliSense Inc.
Yusi Liu
VP of Regulatory Affairs
570 El Camino Real, Suite 200
Redwood City, California 94063

Re: K212957
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, NDC
Dated: July 25, 2022
Received: November 15, 2022

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 (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 Shruti N. Mistry -S

Jennifer Shih 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212957

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 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.

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.

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 BioButton System.

Date Prepared: December 12, 2022

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 (Primary) and NDC (Secondary)

III. Predicate Device

Predicate Device Manufacturer	BioIntelliSense Inc.
Predicate Device Trade Name	BioSticker System
Predicate Device 510(k) Number	K191614

IV. Device Description

The BioButton System 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 BioButton for storage and analysis.

The BioButton System (the System), is an extension of the BioSticker System with the same/similar intended use. The System is intended to monitor physiological parameters of the patient/users for relatively long duration (up to 60 days with medical data collection). The System should now enable the connectivity with the BioButton sensor device (BBN) with the rest of the system components.

The BioButton System consists of a single-use 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. See main components of the BioButton System. The main components of the BioButton System could include the following:

- BioButton Sensor
- BioButton adhesives (accessory)
- Data Exchange Hubs (MDDS)
- Cloud-based data platform (MDDS)

The BioButton System is used to collect physiological information from a patient using the BioButton 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,
- Respiratory rate at rest, and
- Skin temperature

[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.

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. Also using the Offload Software, a report will be generated to be viewed by a healthcare professional. The report is not intended to be viewed by the patient.

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, 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.

VI. Technology Characteristics in Comparison with the Predicate Device

Overview

Comparison Items	BioButton System (New Submission)	BioSticker System (K191614)	Justification of Difference
Product Code	DRG	DRG	Equivalent
Classification	Class II	Class II	Equivalent
Intended 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 symptomatic or biometric data.	The BioSticker System is a 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	Different

Comparison Items	BioButton System (New Submission)	BioSticker System (K191614)	Justification of Difference
	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 use on critical care patients.	skin temperature. Data are transmitted via wireless connection from the BioSticker for storage and analysis. The device is intended for use on general care patients who are 21 years of age or older as a general patient monitor, to provide physiological information. The data from the BioSticker System are intended for use by healthcare professionals as an aid to diagnosis and treatment. The device is not intended for use on critical care patients.	
Prescription Use / OCT	Prescription use only	Prescription use only	Same
Mode of Operation	Continuous operation	Continuous operation	Same
Physical Dimension	41.2x37.5.x5.7mm	81.82 x 37.75 x 8.20 mm	Different
Weight	9.4g	23g	Different
Patient Population	General care patients who are 18 years of age or older	General care patients who are 21 years of age or older	Different
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°	10°C - 40 C°	Equivalent
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	-20 C°- 40 C°	0 C°- 50 C°	Equivalent
Transport & Storage Humidity	10 – 95% RH	10 – 95% RH	Same

Comparison Items	BioButton System (New Submission)	BioSticker System (K191614)	Justification of Difference
Single-use / Multiple-use	Single-use	Single-use	Same
Sterilization	No	No	Same
Re-processing between each use?	No	No	Same
Biologics or drugs?	No	No	Same

Technical Specifications

Comparison Items	BioButton System (New Submission)	BioSticker System (K191614)	Justification of Difference
Battery Operated	Yes	Yes	Same
Battery Life	Up to 60 days	30 days	Equivalent
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 (New Submission)	BioSticker System (K191614)	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

Comparison Items	BioButton System (New Submission)	BioSticker System (K191614)	Justification of Difference
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 / Effectiveness

Comparison Items	BioButton System (New Submission)	BioSticker System (K191614)	Justification of Difference
Heart Rate Range	40-125 Beats per Minute	40-125 Beats per Minute	Same
Heart Rate Accuracy	Mean absolute error of less than 5 Beats per minute (<±5 Beats per minute)	Mean absolute error of less than 5 Beats per minute (<±5 Beats per minute)	Same
Respiratory Rate Range	10-30 Breaths per Minute	10-30 Breaths per Minute	Same
Respiratory Rate Accuracy	Mean absolute error of less than 3 Breaths per Minute (<±3 Breaths per Minute) at rest	Mean absolute error of less than 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 BioSticker 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 this device is determined as a “moderate” level of concern per FDA Guidance Document < Content of Premarket Submissions for Software Contained in Medical Devices> 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" 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 new device • Temperature measurement performance validation per ASTM E1112 standard per 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 shows that the battery life of the device is no less than 30 days
Animal Study	No animal / pre-clinical study was conducted.
Clinical Studies	Clinical studies was performed on general population to confirm the measurement performance for heart rate and respiratory rate.
Human Factor	Human factor engineering and evaluation for BioButton System 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 BioButton System was carried out per the FDA guidance document < Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Draft 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 BioButton device and the predicate device (K191614) do not raise new concerns. Thus, the BioButton Platform and the predicate device (K191614) are substantially equivalent.