January 14, 2022

Capsule Surveillance Technologies, SAS /Capsule Tech, Inc.
Peter Kelley
Director Quality & Regulatory
300 Brickstone Square Suite 203
Andover, Massachusetts 01810

Re: K213335
Trade/Device Name: Capsule Surveillance System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: December 13, 2021
Received: December 15, 2021

Dear Peter Kelley:

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)*

Device Name
Capsule Surveillance System

Indications for Use *(Describe)*
Capsule Surveillance is a clinical decision support device that integrates, analyzes, and displays data from multiple sources including medical devices and healthcare information systems. It uses standardized rules that are based on customers approved clinical practices, protocols, and policies to create clinically relevant alerts in health care facilities when used by clinical physicians or appropriate medical staff under the direction of physicians. It is not intended to replace clinicians' judgment, but rather to assist clinicians in making timely, informed, higher quality decisions.
Capsule Surveillance may be configured for secondary monitoring and alerting intended to be relied upon in deciding to take immediate clinical action.
Capsule Surveillance may also be configured for remote display of physiological data and alerts not intended to be relied upon in deciding to take immediate clinical action.

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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510(k) Summary			
I. SUBMITTER			
Date Prepared	October 1st, 2021		
Submitter/Owner	Capsule Technologies, SAS / Capsule Tech, Inc. FDA Establishment Number: 3003630387 300 Brickstone Square Suite 203 Andover, MA 01810 USA Phone: 978-697-4364		
Key Contact	Peter Kelley Director Quality & Regulatory peter.kelley@philips.com		
510(k) Submission Type	This is a traditional 510(k).		
II. DEVICE			
Trade Name	Capsule Surveillance System		
Common Name	Physiological Monitor		
Classification Name	Panel & Name: Cardiovascular (OHT2) Subpart & Division: Cardiac Electrophysiology, Diagnostics, and Monitoring Devices (DHT2A) 21 CFR 870.2300 Regulatory Class: Class II Product Code: MWI		
III. PREDICATE DEVICE			
Predicate Device	***510(k) No.***	***Company Name*** ***Device Name***	***Product Code***
	K142106	Decisio Health, Inc.'s Decision Health Patient Dashboard	MWI
Reference Device	K130208	Cardiopulmonary Corp.'s Bernoulli Enterprise Software	MHX, MSX, PFY
The Capsule Surveillance System is substantially equivalent to the legally marketed predicate Decision Health, Inc.'s Decision Health Patient Dashboard (K142106).			

IV. DEVICE DESCRIPTION

Capsule Surveillance System – description of the device per 21 CFR 807.92(a) (4)

The Capsule Surveillance System is a clinical decision support device that integrates data from multiple sources including medical devices and healthcare information systems.

The Capsule Surveillance Systems offers two methods of accessing the clinical application:

- A workstation which is a dedicated desktop used exclusively to run the Capsule Surveillance System clinical application in kiosk mode.
- The remote display which is any machine that accesses the Capsule Surveillance System via a web browser.

Use of the Capsule Surveillance System allows for simultaneous monitoring of different patients in a clinical setting, providing information from integrated data sources that monitor physiological parameters such as, pulse, respiratory rate, SpO2, EtCO2, temperature, and blood pressure.

V. INDICATIONS FOR USE

Intended Use as required per 21 CFR 807.92(a)(5)

The Capsule Surveillance is a clinical decision support device that integrates, analyzes, and displays data from multiple sources including medical devices and healthcare information systems. It uses standardized rules that are based on customers approved clinical practices, protocols, and policies to create clinically relevant alerts in health care facilities when used by clinical physicians or appropriate medical staff under the direction of physicians. It is not intended to replace clinicians' judgment, but rather to assist clinicians in making timely, informed, higher quality decisions.

Capsule Surveillance may be configured for secondary monitoring and alerting intended to be relied upon in deciding to take immediate clinical action.

Capsule Surveillance may also be configured for remote display of physiological data and alerts not intended to be relied upon in deciding to take immediate clinical action.

Comparison of Intended Uses for Subject Device and Predicate

Name	**Indications for Use/Intended Use**
Capsule Surveillance System ***Subject Device***	The Capsule Surveillance is a clinical decision support device that integrates, analyzes, and displays data from multiple sources including medical devices and healthcare information systems. It uses standardized rules that are based on customers approved clinical practices, protocols, and policies to create clinically relevant alerts in health care facilities when used by clinical physicians or appropriate medical staff under the direction of physicians. It is

	not intended to replace clinicians' judgment, but rather to assist clinicians in making timely, informed, higher quality decisions. Capsule Surveillance may be configured for secondary monitoring and alerting intended to be relied upon in deciding to take immediate clinical action. Capsule Surveillance may also be configured for remote display of physiological data and alerts not intended to be relied upon in deciding to take immediate clinical action.
K142106 Decisio Health Patient Dashboard ***Predicate***	The Decisio Health Patient Dashboard is a decision support device indicated for aggregating, displaying, and managing physiologic and other patient information. This information is generated by third party medical devices and patient information systems. The device performs automated calculations on patient data collected by third party devices based on approved clinical protocols at patient care facilities. The Decisio Health Patient Dashboard is intended for use by clinicians in healthcare facilities.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Similarities

Item of Comparison	Description/Rationale
Target Populations	Both devices are intended to be used by trained clinicians.
Environment of Use	Both devices are intended to be used in a hospital setting.
Matrix and Detailed Views	Both devices allow for matrix or multi-patient simultaneous monitoring, as well as detailed views/monitoring of single patients.
Data Input	Both devices use input from EMR systems as well as medical devices via HL7 feed for monitoring

Differences

Item of Comparison	Description/Rationale
Methods for Accessing the Application	The subject Capsule Surveillance System allows access via a workstation or remotely via a web browser. The predicate Decisio Health Patient Dashboard allows access through a computer, while also permitting access through a patient monitor or mobile device.

Substantial Equivalence Summary

Operational and technological characteristics form the basis for the determination of substantial equivalence of the Capsule Surveillance System with the legally marketed predicate devices (K142106). The Capsule Surveillance System is substantially equivalent to the predicate devices.

VII. PERFORMANCE DATA

Non-Clinical Tests – Harmonized Standards

The Capsule Surveillance System has passed all safety tests for demonstrated compliance with the harmonized standards below.

Standard	FDA Recognition #	Title #
ANSI AAMI IEC 62304:2006/A1:2016	13-79	Medical device software – Software life cycle processes [Including Amendment 1 (2016)]
ANSI AAMI IEC 62366-1:2015+AMDI:2020 (Consolidated Text)	5-129	Medical devices – Part 1 Application of usability engineering to medical devices, including Amendment 1

Non-clinical Bench Tests

Human factors and usability testing has been completed. Furthermore, testing in compliance with IEC 60601-1-8 for requirements for alarm systems in medical electrical equipment and medical electrical systems was completed, as well as certification to IEC 62304 for software lifecycle and IEC 62366.

No new issues of safety or effectiveness are introduced as a result of using this device.

Clinical Studies

The Capsule Surveillance System, like the predicate device, did not require clinical trials.

FDA recognized standards, FDA guidance documents, harmonized standards, verification and validation, software validation, usability validation, and risk management activities have taken place for the Capsule Surveillance System.

Based upon the design, intended use, indications for use, classification, usability and safety testing the Capsule Surveillance System is substantially equivalent to the listed predicate device.

No new issues of safety or effectiveness are introduced as a result of using this device.

VIII. CONCLUSIONS

The results of the substantial equivalence assessment, taken together with non-clinical bench testing, electrical safety and electromagnetic compatibility, software verification and validation,

human factors and usability demonstrate that the Capsule Surveillance System does not raise additional questions of safety and effectiveness when compared to the predicate, performs as intended, and has performance characteristics that are substantially equivalent to the Decision Health Patient Dashboard predicate device.