September 15, 2023

Siemens Medical Solutions USA Inc.
Patricia Jones
Regulatory Affairs Professional
40 Liberty Boulevard
Malvern, Pennsylvania 19355

Re: K223812
Trade/Device Name: Sensis Vibe (VD15B)
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II
Product Code: DQK, DSJ, DSK, DRQ, DXN, KRB, DQA, FLL, CCK
Dated: December 18, 2022
Received: December 20, 2022

Dear Patricia Jones:

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,

Robert T. Kazmierski -S

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)*
K223812

Device Name
Sensis Vibe Hemo
Sensis Vibe Combo

Indications for Use *(Describe)*
The Sensis Vibe Hemo (VD15B) and Sensis Vibe Combo (VD15B) recording systems are intended to be used as a diagnostic and administrative tool supporting hemodynamic cardiac catheterizations and/or electrophysiology studies, for cardiac as well as interventional radiology and surgical studies. The system is equipped with modules, enabling various configurations ranging from a standalone acquisition unit with limited administrative functionality to multiunit installations with a common database and satellite workstations accessing the data using the administrative tools.

The device is intended to be used on either or both of the following populations:
1. Adult and pediatric populations requiring electrophysiology examinations, typically when the patient is suffering from cardiac arrhythmias.
2. Adult and pediatric populations requiring hemodynamic examinations, typically when the patient has a heart or vascular disease resulting in insufficient hemodynamic functionality.

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.

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510(k) Summary: Sensis Vibe Hemo and Sensis Vibe Combo

Company: Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65
Malvern, PA 19355

Date Prepared: August 14, 2023

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. General Information:

Importer / Distributor:
Siemens Medical Systems USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355
Establishment Registration Number: 2240869

Manufacturing Site:
Siemens AG/Siemens Healthcare GmbH
Siemensstr. 1-OR- Rittigfeld 1
FORCHHEIM Bavaria, DE 91301
Establishment Registration Number: 3004977335

2. Contact Person:

Ms. Patricia D. Jones
Regulatory Affairs Professional
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Phone: (678) 575-8832
Email: patricia.jones@siemens-Healthineers.com

3. Device Name and Classification:

Trade Name:	**Sensis Vibe Hemo (VD15B)** **Sensis Vibe Combo (VD15B)**
Classification Name:	Programmable diagnostic computer
Classification Panel:	Cardiovascular Diagnostic Devices
Regulation Number:	21 CFR §870.1425
Device Class:	Class II
Product Codes:	DQK, DSJ, DSK, DRQ, DXN, KRB, DQA, FLL, CCK

4. Legally Marketed Primary Predicate Device

Trade Name:	**Sensis Vibe (VC12)**
510(k) Clearance	K150493
Clearance Date	June 30, 2015
Classification Name:	Programmable diagnostic computer
Classification Panel:	Cardiovascular Diagnostic Devices

Regulation Number:	21 CFR §870.1425
Device Class:	Class II
Product Code:	DQK
Total Product Life Cycle:	All product Recall incidents are considered during the Design Input phase of development to ensure the latest models will not be affected by any of the applicable issues.

Predicate Device	
Trade Name:	**iLab Polaris-Modality Guidance System**
510(k) Clearance	K191008
Clearance Date	July 02, 2019
Classification Name:	Programmable diagnostic computer
Classification Panel:	Cardiovascular Diagnostic Devices
Regulation Number:	21 CFR §870.1425
Device Class:	Class II
Product Code:	DQK
Subsequent Product Code	DSK, ITX, IYO

Reference Device	
Trade Name:	Datex-Ohmeda S/5 E-PRESTIN Module Family, including E-Prestin, E-Restin, E-PRETN, E-PP, and E-PT/E modules
510(k) Clearance	K051217
Clearance Date	February 03, 2006
Classification Name:	Patient Physiological Monitor (with arrhythmia detector or alarm
Classification Panel:	Cardiovascular Diagnostic Devices
Regulation Number:	21 CFR §870.1025
Device Class:	Class II
Product Code:	MHX

5. Device Description:

SIEMENS Medical Solutions USA, Inc. intends to market the Sensis Vibe Hemo (VD15B) and Sensis Vibe Combo (VD15B), a hemodynamic and electrophysiological recording system. This 510(k) submission describes modifications to the previously cleared Primary Predicate Device the Sensis (K150493). Sensis Vibe Hemo (VD15B) and Sensis Vibe Combo (VD15B) is a multi-channel computer-based stationary system for the measurement, display, and printout of bio-physiological events. There are two configurations for this device: Sensis Vibe-Hemo and Sensis Vibe Combo.

Hemodynamic and electrophysiologic signals such as intracardiac pressure, ECG signals, and intracardiac electrograms (ICEG) are measured and displayed by the system; several hemodynamic calculations are performed based on the measured values of the input signals. These data can be recorded in real-time and stored on removable media or in a digital DICOM archive.

The Sensis Vibe Hemo (VD15B) and Sensis Vibe Combo (VD15B) system is comprised of the following basic hardware components: a small cabinet (video distribution box), front-end electronics, a keyboard with a mouse, and master and slave monitor(s) for real-time presentation of ECG tracings and pressure and ICEG waveforms. The small cabinet (video distribution box) contains power distribution electronics, video drivers, and a separation device for electrical isolation between the small cabinet and the signal input box. The front-end electronics contain modules for the acquisition of invasive blood pressure, ECG, SpO2, CO, and optionally ICEG and NBP, and are normally stalled at the operating table.

The following modifications are made to the cleared Predicate Device: Sensis system:

1) Updated system Software/Hardware from VC12 to VD15B

   A. Added a temperature display (measured by third-party temperature probes) with the use of an adapter cable that connects to the HiSiB.

   B. Introduction of Diastolic Hyperemia-Free Ratio (DFR^{TM}) assessment of blood flow through single or multiple lesions without inducing hyperemia.

2) Updated the Indications for Use Statement to include the Subject Device Marketing Name: Sensis Vibe Hemo (VD15B) and Sensis Vibe Combo (VD15B).

3) Updated 510(k) Information for Primary Predicate Device

6. Indications for Use:

The Sensis Vibe Hemo (VD15B) and Sensis Vibe Combo (VD15B) recording systems are intended to be used as a diagnostic and administrative tool supporting hemodynamic cardiac catheterizations and/or electrophysiology studies, for cardiac as well as interventional radiology and surgical studies. The system is equipped with modules, enabling various configurations ranging from a standalone acquisition unit with limited administrative functionality to multiunit installations with a common database and satellite workstations accessing the data using the administrative tools.

The device is intended to be used on either or both of the following populations:

1. Adult and pediatric populations requiring electrophysiology examinations, typically when the patient is suffering from cardiac arrhythmias.
2. Adult and pediatric populations requiring hemodynamic examinations, typically when the patient has a heart or vascular disease resulting in insufficient hemodynamic functionality.

7. Substantial Equivalence:

The Sensis Vibe Hemo (VD15B) and Sensis Vibe Combo (VD15B) Electrophysiological and Hemodynamic Recording System with software VD15B are

substantially equivalent to the commercially available Siemens Sensis which was described in premarket notification K150493 which received 510(k) clearance on June 30, 2015. (See **Table 1** below):

Table 1: Predicate Device Comparable Properties for Subject Device Modifications:

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Comparable Properties
Primary Predicate	K150493	06/30/2015	• Indications for use • All Functionality
Siemens : Sensis **Product Code:** DQK			
Predicate Device:	K191008	07/02/2019	• DFR™
Boston Scientific: iLab Polaris-Modality Guidance System **Product Codes**: DQK, DSK, IYO, ITX			
Reference Device:	K051217	02/03/2006	• Temperature
GE : E-PRESTIN Multi-parameter Hemodynamic Module **Product Code**: MHX			

8. Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:

Technological differences between the Subject Device and the Predicate Devices are provided in **Table 2** below for all modifications.

Table 2: Summary of Comparison of Technological Characteristics

Modifications	Subject Device Sensis Vibe Hemo (VD15B) and Sensis Vibe Combo (VD15B)	Primary Predicate Device Sensis (VC12) (K150393)	Comparison Results
New System Software Changes	1. Updated system Software from VC12 to VD15B	System Software Version (VC12)	**Comparable:** The addition of a temperature display with the use of an adapter cable is a change from the primary predicate device. Testing was performed and test results indicate this feature does not raise any new safety or effectiveness issues.
	A. Added a temperature display (measured by third-party temperature probes) with the use of an adapter cable that connects to the HiSiB.	No Temperature display	
	B. Introduction of Diastolic Hyperemia-Free Ratio™ (DFR™) assessment of blood flow through single or multiple lesions without inducing hyperemia.	**Predicate Device iLabs Polaris Multi-Modality Guidance System K191008**	**Comparable:** The algorithm used to calculate DFR™ has the same measuring points. Testing was performed and test results indicate this feature does not raise any new safety or
		Diastolic Hyperemia-Free Ratio (DFR™) assessment of blood flows through single or multiple lesions without inducing hyperemia.	

Modifications	Subject Device Sensis Vibe Hemo (VD15B) and Sensis Vibe Combo (VD15B)	Primary Predicate Device Sensis (VC12) (K150393)	Comparison Results
			effectiveness issues.
IFU Statement	2. Revised IFU Statement		**Comparable:** Same as Primary Predicate Device except for the Name change from "Sensis" to "**Sensis Vibe Hemo (VD15B) and Sensis Vibe Combo (VD15B)**" Corrected verb usage typos.
Update 510(k) Information	3. Update 510(k) Information for Primary Predicate Device is provided in **Volume 011.**		

The subject devices, the Sensis Vibe Hemo (VD15B) and Sensis Vibe Combo (VD15B), do not affect the intended use of the device nor does it alter its fundamental scientific technology from the 510(k) cleared predicate device. Non-clinical and bench-testing information supports the new extended functionality of the Sensis Vibe Hemo (VD15B) and Sensis Vibe Combo (VD15B), which is provided in **Volume 020.**

9. Conformity to Standards and Nonclinical Performance Testing:

Siemens claims conformance to a signed statement of conformance to the following performance standards:

Recognition #	Product Area	Title of Standard	Reference Number and Date	Standards Development Organization
2-258	Biocompatibility	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	10993-1:2018	ISO
5-134	General I (QS/ RM)	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	15223-1:2021	ISO
14-579	Sterility	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices.	17664-2:2021	ISO
15-135	General I (QS/RM)	Medical devices - Information to be supplied by the manufacturer	20417:2021	ISO
5-129	General	Medical devices - Part 1: Application of usability engineering to medical devices	62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	IEC

Recognition #	Product Area	Title of Standard	Reference Number and Date	Standards Development Organization
13-83	Software/ Informatics	Principles for medical device security - Risk management.	TIR57:2016	AAMI
19-4	General	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]	ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Consolidated Text)	ANSI AAMI
19-8	General	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances --Requirements and tests	60601-1-2 Edition 4.0:2014-02	IEC
5-76	General	Medical Electrical Equipment - Part 1-8: General Requirements for Basic Safety And Essential Performance - Collateral Standard: General Requirements, Tests And Guidance For Alarm Systems In Medical Electrical Equipment And Medical Electrical Systems	60601-1-8 Edition 2.1 2012-11	IEC
12-273	Radiology	Safety of laser products - Part 1: Equipment classification, and requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]	60825-1:2014 (recognized: 2007)	IEC
5-104	General	Graphical symbols for electrical equipment in medical practice	TR 60878 Ed. 3.0 b:2015	IEC
13-79	Software/ Informatics	Medical Device Software – Software Life Cycle Processes	62304 Edition 1.1 2015-06 Consolidated Version	IEC
3-105	Cardiovascular	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs	60601-2-25 Edition 2.0 2011-10	IEC
3-115	Cardiovascular	Medical electrical equipment - Part 2-34: Particular requirements for the basic safety including essential performance of invasive blood pressure monitoring equipment	60601-2-34 Edition 3.0 2011-05	IEC
1-140	Anesthesiology	Medical electrical equipment – Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors	80601-2-55 Second edition 2018-02	ISO
6-421	General	Medical electrical equipment – Part 2-56: Particular requirements for the basic safety and essential performance of clinical thermometers for body temperature measurement [Including: Amendment 1 (2018)].	80601-2-56 Second edition: 2017-03	ISO
1-139	Anesthesiology	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	80601-2-61 Second Edition 2017-12 (Corrected version 2018-02)	ISO

Recognition #	Product Area	Title of Standard	Reference Number and Date	Standards Development Organization
3-123	Cardiovascular	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers	80601-2-30: Edition 2.0 2018-03	IEC
13-38	Software/Informatics	Application of risk management for IT-networks incorporating medical devices - Part 1: Roles, responsibilities and activities (IEC 80001-1:2010) / Endorsement notice	80001-1 Edition 1.0 2010-10	IEC
13-104	Software/Informatics	Standard for Safety, Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems	2900-2-1 First Edition 2017	ANSI UL
13-96	Software/Informatics	Standard for Safety, Standard for Software Cybersecurity Network-Connectable Products, Part 1: General Requirements	2900-1 First Edition 2017	ANSI UL
5-125	General	Medical devices - Application of risk management to medical devices	14971:2019	ISO
Sensis Vibe complied with the following additional standards currently not recognized				
N/A	N/A	Medical Electrical Equipment: Safety of Multifunction Patient Monitoring Equipment	80601-2-49:2018	IEC
N/A	N/A	Digital Imaging and Communications in Medicine (DICOM)	12052:2017	ISO
N/A	N/A	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	60601-1:2021	IEC
N/A	N/A	Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design	60601-1-9:2020	IEC
N/A	N/A	Degrees of protection provided by enclosures (IP code).	60529:2015	IEC
N/A	N/A	Systems and software engineering - Systems and software Quality Requirements and Evaluation (SQuaRE) - System and software quality models.	25010:2011	ISO IEC
N/A	N/A	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances	63000:2016	IEC
N/A	N/A	Standard for Safety for Information Technology Equipment - Safety - Part 1: General Requirements / national adoption of IEC 60950a-1 with modifications and revision of ANSI/UL	60950-1:2014	ANSI UL

Recognition #	Product Area	Title of Standard	Reference Number and Date	Standards Development Organization
		60950-1-2011 / Approved 2014-10-14 ANSI.		
N/A	N/A	Plastics - Generic identification and marking of plastics products	11469:2016	ISO
N/A	N/A	Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment	62353:2014	ISO

The modifications described in this Premarket Notification are supported with verification and validation testing.

Verification and Validation:
Software Documentation for a Major Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005, and "Off-The-Shelf Software Use in Medical Devices" is also included as part of this submission. The performance data demonstrate continued conformance with special controls for medical devices containing software.

Non-clinical tests were conducted on Sensis Vibe Hemo (VD15B) and Sensis Vibe Combo (VD15B) Systems during product development.

The bench test study is performed to demonstrate that Sensis Vibe Hemo (VD15B) and Sensis Vibe Combo (VD15B) DFR index is numerically equivalent to iLab Polaris Modality Guidance System's DFR index. In the bench test study, DFR indices obtained from Sensis Vibe Hemo (VD15B), and Sensis Vibe Combo (VD15B) are compared with DFR indices obtained from the bench test study performed and submitted for iLab Polaris-Modality Guidance System (K191008).

The Risk analysis was completed, and risk control was implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria. Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

Sensis Vibe Hemo (VD15B) and Sensis Vibe Combo (VD15B) were tested and found to be safe and effective for intended users, uses, and use environments through the design control verification and validation process. The Human Factor Usability Validation showed that Human factors are addressed in the system test according to the operator's manual. Customer employees are adequately trained in the use of this equipment.

Siemens conforms to the cybersecurity requirements by implementing a process of preventing unauthorized access, modifications, misuse or denial of use, or the unauthorized use of information that is stored, accessed or transferred from a medical

device to an external recipient. Provided in this submission is a cybersecurity statement that considers IEC 80001-1:2010. The responsibility for compliance with IEC 80001-1-2010 is the hospital. Provided in the Software Section is the required cybersecurity information.

Summary:

Performance tests were conducted to test the functionality of the Sensis Vibe Hemo (VD15B) and Sensis Vibe Combo (VD15B) Systems. These tests have been performed to assess the functionality of the subject device. The results of all conducted testing and clinical assessment were found acceptable and do not raise any new safety or effectiveness issues.

10. General Safety and Effectiveness Concerns:

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device safely and effectively.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification, and validation testing. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practices, and all equipment is subject to final performance testing.

11. Conclusion as to Substantial Equivalence:

The predicate devices were cleared based on non-clinical supportive information and data. Similar non-clinical test results demonstrate that the Sensis Vibe Hemo (VD15B) and Sensis Vibe Combo (VD15B) Systems acceptance criteria are adequate for the intended use of the device. The comparison of technological characteristics, non-clinical performance data and software validation data demonstrates that the Subject Device is as safe and effective when compared to the Predicate Devices that are currently marketed for the same intended use.