DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 30, 2015

Siemens Medical Solutions, Inc.
Patricia Jones
Regulatory Specialist
51 Valley Stream Parkway
Malvern, Pennsylvania 19355

Re: K150493
    Trade/Device Name: Sensis
    Regulation Number: 21 CFR 870.1425
    Regulation Name: Programmable Diagnostic Computer
    Regulatory Class: Class II
    Product Code: DQK
    Dated: May 28, 2015
    Received: May 29, 2015

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address
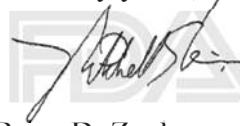http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to
http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SIEMENS

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150493

Device Name

Sensis

Indications for Use *(Describe)*

The Sensis recording system is intended to be used as a diagnostic and administrative tool supporting hemodynamic catheterizations and/or electrophysiology studies, for cardiac as well as interventional Radiology as well as surgical studies. The system is equipped by modules, enabling various configurations ranging from a stand-alone 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.

510(k) Summary: Sensis

Company: Siemens Medical Solution USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: February 24, 2015

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 Solution USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Establishment Registration Number:
2240869

Manufacturing Site:
SIEMENS AG Sector Healthcare
Siemensstraße 1
D-91301 Forchheim, Germany

Establishment Registration Number:
3004977335

2.   Contact Person:
Ms. Patricia D Jones
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway   D-02
Malvern, PA 19355
Phone: (610) 448 -3536   Fax: (610) 448-1787
Email: patricia.d.jones@siemens.com

3.   Device Name and Classification:
Trade Name: Sensis
Classification Name: Programmable diagnostic computer
Classification Panel: Cardiovascular Diagnostic Devices
CFR Section: 21 CFR §870.1425

Device Class: Class II
Product Code: DQK

4.   **Legally Marketed Primary Predicate Device**
       Trade Name: AXIOM Sensis
       510(k) #:   K131812
       Clearance Date: July 25, 2013
       Classification Name: Programmable Diagnostic Computer
       Classification Panel: Cardiovascular Diagnostic Devices
       Classification Regulation: 21 CFR §870.1425
       Device Class: Class II
       Product Code: DQK
       Recall Information: N.A.

       Legally Marketed Secondary Predicate Device
       Trade Name: Cathcor Desktop
       510(k) #:   K002137
       Clearance Date: October 5, 2000
       Classification Name: Programmable Diagnostic Computer
       Classification Panel: Cardiovascular Diagnostic Devices
       Classification Regulation: 21 CFR §870.1425
       Device Class: Class II
       Product Code: DQK
       Recall Information: N.A.

5.   **Device Description:**
       Reason for Submission:

       Siemens Medical Solutions USA, Inc. intends to introduce the Sensis Electrophysiological and Hemodynamic Recording System with updated software VC12B. This 510(k) submission describes several modifications to the previously cleared predicate device the Sensis Electrophysiological and Hemodynamic Recording System (K131812) cleared on July 25, 2013.

       The following modifications are made to the cleared Sensis system:
       1). Updated Indication for Use Statement to be more descriptive to include: ("Interventional Radiology including surgery").
       2). Addition of a DrugMed Calculator – may be used to compute calculations for the drug amount dosage and Creatinine clearance.
       3). Update 510(k) Information for the predicate 510(k) (**Appendix E**).

       Sensis is a multi-channel computer-based stationary system for the measurement, display, and printout of bio-physiological events. Hemodynamic and electrophysiological signals such as intracardiac pressure, ECG signals, and intracardiac electrograms (ICEG) are

measured and displayed by the system. Sensis software provides the ability to monitor and assess invasive blood pressure, ECG signals, and optionally intracardiac electrograms (ICEG) The user can perform a number of calculations based on manual input and / or on the input signals and other hemodynamic parameter values from the Sensis system.

The Sensis System can be used also for vascular procedures in interventional radiology and surgery the same way as for cardiac procedures in interventional cardiology. The Sensis functionality remains the same.

For more flexibility in the department, additional post processing and reporting workplaces can always be connected to the network.

A Drug Med Calculator has been added to the Sensis. It uses established formulas which could also be used in Siemens secondary predicate the Cathcor system. The Drug Med Calculator provides a workflow improvement for the users and allows ease calculations for the drug amount dosage and creatinine clearance. The implementation of the Drug Med Calculator does not raise new issues of safety or effectiveness of the subject device.

Provided in **Sections 5 and 14** of this 510(k) submission, is a completed "510(k) Decision Making FlowChart". We believe these modifications are eligible for the Traditional 510(k) process since the subject device has the same fundamental scientific technology, Intended Use and general Indications for Use as the predicate device system. The new descriptive Indications for Use statement is supported with non-clinical testing in support of a claim of substantial equivalence to Siemens' predicate device the Sensis hemodynamic and electrophysiological recording system (K131812).

6.   **Indication for Use:**
The Sensis recording system is intended to be used as a diagnostic and administrative tool supporting hemodynamic catheterizations and/or electrophysiology studies, for cardiac as well as interventional Radiology as well as surgical studies. The system is equipped by modules, enabling various configurations ranging from a stand-alone 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 Electrophysiological and Hemodynamic Recording System with software VC12B is substantially equivalent to the commercially available Siemens Sensis which was described in premarket notification K131812 which received 510(k) clearance on July 25, 2013. (See Table 4 below):

The formula for Drug Med Calculator is the same as used with Siemens Cathcor which was described in premarket notification K002137 which received 510(k) clearance on October 5, 2000. (See **Table 4** below):

Table 2: Predicate Device Comparable Properties to Subject Device

Predicate Device(s) Name and Manufacturer	510(k) Number	Clearance Date	Comparable Properties
Primary Predicate Device : Siemens Sensis SW VC12A Product Codes: DQK	K131812	07/25/2013	Indications for use Acquisition Monitoring Recording Imaging Administrative Functions
Secondary Predicate Device : Cathcor Product Code: DQK	K002137	10/05/2000	Formula for Drug Med Calculator

The subject device, the Sensis VC12B, does 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 information and Referenced literature supports the new descriptive indications for use statement and the formula for Drug Med Calculator for the Sensis system (see **Appendix F** and **Attachment 9**).

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

The Sensis Electrophysiological and Hemodynamic Recording System with software VC12B with extended intended use is the same as the predicate SW VC12A. The Sensis features the same Acquisition, Monitoring, Recording, Imaging and Administrative Functions as the predicate Sensis. It interfaces with Angiography X-ray systems e.g. Artis

Q, Artis Q zen, Artis zee / zeego. The user function is the same as the predicate Sensis device. The modified Indication for Use Statement which is more descriptive, does not change the hardware or software of the primary predicate device.

The Drug Med Calculator of the Sensis uses the same formula as used with Siemens secondary predicate Cathcor system and provides calculations for the drug amount dosage and creatinine clearance. This feature is added to the primary predicate device (K131812- Sensis) and does impact software. Software information specific to the Drug Med Calculator is provided in accordance to "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005 in **Attachment 9** of this submission.

The subject device has the same technological characteristics (see **Table 2** Comparable properties) as the primary and secondary predicate devices. The technological characteristics do not differ from the primary and secondary predicate devices, as explained above.

9.   **Non-Clinical Testing:**
Non-clinical tests were conducted for the Sensis Electrophysiological and Hemodynamic Recording System during product development. The modifications described in this Premarket Notification were supported with verification and validation testing. Siemens claims conformance to the following performance standards and: 60601-1; 14971; 62366; 60601-1-6; 60601-1-2; 60601-1-8; PS 3.1 - 3.20; 60601-2-25; IEC 60601-2-34; 80601-2-61; 80001-1; 80601-2-30; 60601-2-49 as provided in **Section 11**.

Electrical safety and Electromagnetic Compatibility (EMC) testing were conducted on the Electrophysiological Monitoring and Recording System, consisting of the computers, monitors, video distribution components, and signal acquisition components. The Sensis system was certified by a third party laboratory to comply with the IEC 60601-1, IEC 60601-2-25, IEC 80601-2-30, IEC 60601-2-34, IEC 80601--61 standards for safety and the IEC 60601-1-2 standard for EMC. All tests passed.

Verification and Validation:
Software Documentation for a Moderate 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 is also included as part of this submission. The performance data demonstrates continued conformance with special controls for medical devices containing software. Nonclinical tests (**Section 21)** were conducted on the Sensis System during product development. The Risk analysis was completed and risk control implemented to mitigate identified hazards.   The testing results supports that all the software specifications

have met the acceptance criteria. Testing for verification and validation for the device was found acceptable to support the claims of substantial equivalence.

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. Contained in **Attachment 8** of this submission is a cybersecurity statement that considers IEC 80001-1:2010. The responsibility for compliance with IEC 8001-1-2010 is the hospital. Provided in the Software section, (**Section 18**) and the Operator's Manual (**Appendix B**) is the required cybersecurity information.

Summary:

Performance tests were conducted to test the functionality of the Sensis Electrophysiological and Hemodynamic Recording System. These tests have been performed to assess the functionality of the subject device. Results of all conducted testing were found acceptable in supporting the claim of substantial equivalence.

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 in a safe and effective manner.

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, and mechanical hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing. Furthermore the operators are health care professionals familiar with and responsible for the evaluating and post processing of X-ray images.

11. Conclusion as to Substantial Equivalence:

The predicate device was cleared based on non-clinical supportive information. The results of these tests demonstrate that Sensis acceptance criteria are adequate for this intended use. The comparison of technological characteristic, non-clinical performance data and software validation data demonstrates that the subject device is as safe, and effective when compared to the predicate device that is currently marketed for the same intended use.