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

December 13, 2016

St. Jude Medical
Marlene Peterson
Sr. Regulatory Affairs Manager
One St. Jude Medical Drive
St. Paul, Minnesota 55117

Re: K162643
Trade/Device Name: MediGuide Technology System (Version 17.0)
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: September 20, 2016
Received: September 22, 2016

Dear Marlene Peterson:

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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162643

Device Name
MediGuide™ Technology System Version 17.0

Indications for Use *(Describe)*
The MediGuide™ Technology system is intended for the evaluation of vascular and cardiac anatomy. It is intended to enable real time tip positioning and navigation of a MediGuide Enabled™/Sensor Enabled™ (equipped with a magnetic sensor) invasive device used in vascular or cardiac interventions in the Cath Lab environment, on both live fluoroscopy or recorded background. The System is indicated for use as an adjunct to fluoroscopy.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) Summary	
510(k) Number	K162643
Submitter Information:	
Date Prepared:	November 7, 2016
Manufacturer	St. Jude Medical
Name &Address:	One St. Jude Medical Drive St. Paul, MN 55117
Contact Person:	Marlene Peterson Sr. Regulatory Manager Phone (651) 756-3268 Fax (651) 756-3301 mpeterson07@sjm.com
Device Information:	
Trade Name:	MediGuide™ Technology System Version 17.0
Common Name:	Programmable Diagnostic Computer
Classification Name:	870.1425, computer, diagnostic, programmable
Product Code:	DQK
Class:	Class II
Predicate Device:	K120301-MediGuide™ Technology System
Reference Applications	K160335 – Advisor™ FL, Circular Mapping Catheter, Sensor Enabled™ K160210 – EnSite Precision™ Cardiac Mapping System
Device Description:	MediGuide Technology enables navigation of devices on pre-recorded X-ray images allowing the physician to reduce the duration of live X-ray during a procedure. MediGuide Technology applies 3D visualization and precise navigation to pre-recorded 2D X-ray images and can be used by the physician to perform complex electrophysiology procedures and CRT implants. MediGuide Technology is analogous to a global positioning system (GPS) in that it uses a low powered electromagnetic field to locate device-based sensors in three-dimensional space. The system uses this location information to overlay MediGuide™ Enabled/Sensor Enabled™ devices on the corresponding pre-recorded X-ray image, which allows the physician to reduce the duration of live X-ray during a procedure. MediGuide creates a real-time clinical environment by compensating for patient motion, respiration and heart rate variability
Intended Use: (Indications for Use)	The MediGuide™ Technology system is intended for the evaluation of vascular and cardiac anatomy. It is intended to enable real time tip positioning and navigation of a MediGuide Enabled™/Sensor Enabled™ (equipped with a magnetic sensor) invasive device used in vascular or cardiac interventions in the Cath Lab environment, on both live fluoroscopy or recorded background. The System is indicated for use as an adjunct to fluoroscopy.
Comparison to Predicate Devices	The proposed MediGuide™ Technology System software version v17.0 has the same intended use and fundamental scientific technology as the predicate device, MediGuide™ Technology cleared under MediGuide™ Technology System K120301 (decision date on Feb 24 2012). The modified MediGuide™ Technology System is identical to the cleared device (K120301), with the following modifications:

510(k) Summary	
510(k) Number	K162643
	• Upgrading of operation system from Microsoft Windows XP to Microsoft Windows 7 • Updates to existing software features and bug fixes • Introducing the new hardware , MediGuide ™ Sensor Enabled Devices • Minor hardware change to (elimination of one computer and corresponding routing changes) • New MediGuide™ Cath Connect, Sensor Enabled™ hardware unit compatible with Sensor Enabled™ Device • Updated Indications for Use for compatibility with Sensor Enabled™ devices
Summary on Non-Clinical Testing	MediGuide™ Technology System has the same intended use as the predicate device. The technological characteristic for the devices are the same as predicate devices. Design verification activities for functional testing were performed with their respective acceptance criteria to ensure that software modifications and hardware addition do not affect the safety or effectiveness of the device. All testing performed met the established performance specifications. The changes to the application software and operating system were evaluated through software verification and validation to show that the application software is acceptable for use and meets requirements. The MediGuide™ Technology System v17.0 is developed and tested in accordance with the following industry guidance documents and standards: • Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices • Content of Premarket Submissions for Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff • 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" is included as part of this submission. The MediGuide™ Technology System conforms to the following standards: • EN ISO 14971 (2012) Medical Devices – Applications of risk management to medical devices IEC 60601-1 (2005 + CORR.1 (2006) + CORR.2 (2007) + AM1:2012) Medical electrical equipment- Part 1: General requirements for basic safety and essential performance • IEC 60601-1-2 (2007) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: electromagnetic disturbances - requirements and tests • IEC 62304 (2006) Medical Device Software- Software Life Cycle Process

510(k) Summary	
510(k) Number	K162643
	• IEC 62366 (2007) Medical devices – Application of usability engineering to medical devices A non GLP study confirming customer requirements and system compatibility was conducted. <u>Risk Management</u> The changes to the application software and operating system were evaluated through review of risk management to ensure no new hazards have been introduced by this change. The risk analysis was completed and risk controls were implemented to mitigate identified hazards.
Statement of Equivalence	The MediGuide™ Technology System v17.0 has the same intended use as the predicate device. The technological characteristics for the device are the same as the predicate device. Based on this and the data provided in this pre-market notification, the subject device and predicate device have been shown to be substantially equivalent.