DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 22, 2015

St. Jude Medical
Melissa Frank
Senior Regulatory Affairs Specialist
One St. Jude Medical Drive
St. Paul, MN 55117

Re: K151911
Trade/Device Name: WorkMate Claris System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: September 17, 2015
Received: September 22, 2015

Dear Melissa Frank:

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.

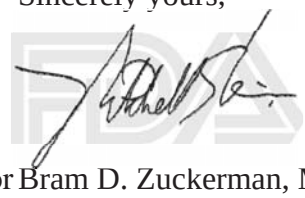
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

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)*
K151911

Device Name
WorkMate Claris™ System

Indications for Use *(Describe)*
The WorkMate Claris™ System is indicated for use during clinical electrophysiology procedures.

The WorkMate Claris™ System is a fully computerized system for capturing and measuring physiological data in the clinical electrophysiology (EP) laboratory. It provides digital signal acquisition and display of those electrical signals on high resolution monitors.

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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ST. JUDE MEDICAL

510KSUMMARY

510(k) Number	K151911
Date Prepared	09-July-2015
Submitter Information	
Manufacturer Name/Address	St. Jude Medical One St. Jude Medical Drive St. Paul, MN 551177
Contact Person	Melissa Frank Sr. Regulatory Affairs Specialist Phone (651) 756-2954 Mfrank02@sjm.com
Device Information	
Trade Name	WorkMate Claris™ System
Common Name	Programmable Diagnostic Computer
Class	II
Classification Name	870.1425, computer, diagnostic, programmable DQK
Predicate Device	WorkMate Claris System K132073
Device Description	The WorkMate Claris System is a fully computerized system for capturing and measuring physiological data in the clinical electrophysiology (EP) laboratory. It provides digital signal acquisition and display of those electrical signals on high resolution monitors. The WorkMate Claris System is connected to electrophysiology catheters that are guided into various locations within the heart, and to surface electrocardiogram (ECG) cables. Intracardiac and ECG signals are then acquired from electrodes on the indwelling catheters and ECG leads connected to the amplifier, which amplifies and conditions the signals before they are received by the WorkMate Claris System computer for display, measurement and storage. During the procedure, cardiac signals are acquired and an automated software waveform detector (trigger) performs online recognition of cardiac activation on preselected leads. Temporal interval measurements are computed on a beat-by-beat basis on multiple channels and dynamically posted on the Real Time display. Intervals are calculated between waveforms from the same source on a specific channel (intra-channel measurements) and from multi-source signals across two or more channels (inter-channel measurements). Signals are also presented on a review monitor for measurement and analysis. Continuous capture of the digitized signals can be invoked, and the user can also retrieve and display earlier passages of the current study without interruption of the real-time display. The system can also acquire, display and record data from other interfaced devices in use during the procedure, such as imaging devices and ablation generators.

	The WorkMate Scribe™ Module is an optional integrated monitoring and review station for the WorkMate Claris System that allows a separate user to review and edit current patient study data stored on the WorkMate Claris System and monitor patient data from the WorkMate Claris System during the patient study. The WorkMate Scribe Module consists of a PC, a touch screen LCD monitor and cart connected via Ethernet to a WorkMate Claris System. Vital signs measurements can be imported from an optional external Physiological Module (Smiths Medical Advisor™ Vital Signs Monitor herein referred to as Physio Monitor).
Indications for Use	The WorkMate Claris System is indicated for use during clinical electrophysiology procedures The WorkMate Claris™ System is a fully computerized system for capturing and measuring physiological data in the clinical electrophysiology (EP) laboratory. It provides digital signal acquisition and display of those electrical signals on high resolution monitors.
Predicate Comparison	The proposed WorkMate Claris System software upgrade v1.1, which includes the WorkMate Scribe Module, has the same intended use and fundamental scientific technology as the predicate device, WorkMate Claris System v1.0. The WorkMate Claris and WorkMate Scribe software v.1.1 software upgrade has four main objectives: 1. The main objective for the software upgrade is to update the operating system from Window XP to Windows 7. Microsoft announced that Windows XP has ended life and Microsoft will not continue to support Windows XP. 2. The second objective for the software upgrade is to add a few minor new customer enhancement software features that have been identified through voice of customer (VOC). 3. The third objective of the upgrade is to address software anomalies that were identified either through in-house testing or product surveillance. 4. The fourth objective of the upgrade is to update the Software of Unknown Provenance (SOUP)/ Off-the-Shelf (OTS) programs
Non-Clinical Testing Summary	Design verification activities for functional testing were performed with their respective acceptance criteria to ensure that the software modifications do not affect the safety or effectiveness of the device. All testing performed met the established performance specifications. Performance tests were conducted to test the functionality of the WorkMate Claris™ 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. The WorkMate Claris System software is developed and tested in accordance with the following industry guidance documents and standards: • FDA Reviewers and Compliance on Off-the-Shelf Software used in Medical Devices and IEC 62304 OTS classification • Guidance for the Content of Premarket Submissions for Software

	Contained in Medical Devices • IEC 62304:2006 Medical Device Software - Software Life Cycle Processes • 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. Software Documentation for OTS software classified as a Minor Level of Concern, Class B according the FDA guidance, FDA Reviewers and Compliance on Off-the-Shelf Software used in Medical Devices and IEC 62304 OTS classification is included as part of this submission. 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 the requirements. The WorkMate Claris System conforms to the following standards: • 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 60601-1 (2005 + CORR.1 (2006) + CORR.2 (2007)) Medical electrical equipment- Part 1: General requirements for basic safety and essential performance • ISO 14971 (2012) Medical Devices – Applications of risk management to medical devices • IEC 62366 (2007) Medical devices – Application of usability engineering to medical devices <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. The WorkMate Claris™ System conforms to the Cybersecurity requirements through the cybersecurity risk management process comprised of a risk assessment, risk control, and maintenance of cybersecurity activities.
Statement of Equivalence:	The WorkMate Claris System which includes the WorkMate Scribe Module has the same indications for use as the predicate devices. The technological characteristics for the devices are the same as the predicate devices. Based on this and the data provided in this pre-market notification, the subject devices and predicate devices have been shown to be substantially equivalent.