March 11, 2021

Abbott
Ed Sandberg
Senior Regulatory Affairs Specialist
One St. Jude Medical Drive
St. Paul, Minnesota 55117

Re: K210392
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: February 9, 2021
Received: February 10, 2021

Dear Ed Sandberg:

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,

Aneesh Deoras
Assistant Director (Acting)
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)*
K210392

Device Name
WorkMate Claris™ System

Indications for Use *(Describe)*
The WorkMate Claris™ System is indicated for the 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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510(k) Information	
510(k) Number	K210392
510(k) Type	Special 510(k)
Date Prepared	February 9th, 2021
Submitter Information	
Manufacturer Name/Address	Abbott One St. Jude Medical Drive St. Paul, MN 55117
Contact Person	Ed Sandberg Regulatory Affairs Specialist Phone: 651-245-8398 ed.sandberg@abbott.com
Device Information	
Trade Name	Workmate Claris™ System v1.2
Common Name	Programmable Diagnostic Computer
Class	II
Classification Name	870.1425, computer, diagnostic, programmable
Product Code	DQK
Predicate Device	Workmate Claris™ System v1.1 (K151911)
Reference Applications	N/A
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. The cardiac stimulator integrated with the parent recording system, sends electrical impulses to indwelling catheters through the Amplifier. 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.
Indications for Use	**Workmate Claris™ System v1.2** WorkMate Claris™ System is indicated for the use during clinical electrophysiology procedures. 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.
Submission History	No prior submissions have been made to FDA for the device that is the subject of this submission.
Predicate Comparison	
Comparison	The WorkMate Claris™ System v.1.2, subsystems, and optional ancillary modules, WorkMate™ Scribe™ Module and WorkMate™ Unity™ Review Module, use the same fundamental scientific technology, intended use, and indications as the predicate device. The changes are limited to the modification of system software to support an operating system update to Windows® 10, to manage end of life components, security updates/enhancements, and address software bug fixes. There are no new or increased risks that result from the modifications and the changes do not raise any new questions of safety and effectiveness in regards to the subject device. The modifications for the subject device are outlined below.

Characteristic	**Predicate Device (K151911)**	**Subject Device (K210392)**
H700123, H700124; WorkMate Claris™ System and H700120, H700121 WorkMate™ Scribe™ Module		
Trade / Proprietary Name	WorkMate Claris™ System	Same
Device Class	II	Same
Classification Name	Computer, Diagnostic, Programmable	Same
Product Code	DQK	Same
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.	Same

Characteristic	Predicate Device (K151911)	Subject Device (K210392)
H700977; WorkMate Claris Display Workstation		
Software Version	v1.1.1	v1.2
Workstation Hardware	HP z620	HP z440
H701060, WorkMate™ Scribe™ Display Workstation		
Software Version	v1.1.1	v1.2
Workstation Hardware	HP 8200	Onyx-1723
H800007; WorkMate Claris™ System Software Upgrade Kit v1.2 (z440)		
Operating System	Windows 7	Windows 10
Software Version	v1.1.1	v1.2
Acrobat Reader	v.11.0.06	v.20.006.20042
Bomgar Client (SJMConnect)	v. 14.3.1	v19.1.7
McAfee Application Control	v.8.0.0.817	v.8.2.1.407
Microsoft Word	v. 15.0.4420.1017	v. 16.0.10359.20023
Microsoft Power Point	v. 15.0.4420.1017	v. v. 16.0.10359.20023
H800008; WorkMate™ Scribe™ Module Software Version 1.2		
Operating System	Windows 7	Windows 10
Software Version	v1.1.1	v1.2
Acrobat Reader	v.11.0.06	v.20.006.20042
Bomgar Client (SJMConnect)	v. 14.3.1	v19.1.7
McAfee Application Control	v.8.0.0.817	v.8.2.1.407
Microsoft Word	v. 15.0.4420.1017	v. 16.0.10359.20023
Microsoft Power Point	v. 15.0.4420.1017	v. v. 16.0.10359.20023

Characteristic	Predicate Device (K151911)	Subject Device (K210392)
Software License	N/A	Single License Kit to enable The WorkMate™ Unity™ (H702321) Module Software.
H800010; WorkMate™ Unity™ Module Software Kit Installation v1.2 (10 License)		
Software License	N/A	New model numbers created for Software License Kits for the v1.2 Unity software (10 License)
H800011; WorkMate™ Unity™ Module Software Kit Installation v1.2 (Site License)		
Software License	N/A	Single License Kit to enable The WorkMate™ Unity™ (H702321) Module Software.
H800012; WorkMate Claris™ System Software Upgrade Kit v1.2 (z620)		
Operating System	Windows 7	Windows 10
Software Version	v1.1.1	v1.2
Acrobat Reader	v.11.0.06	v.20.006.20042
Bomgar Client (SJMConnect)	v. 14.3.1	v.19.1.7
McAfee Application Control	v.8.0.0.817	v.8.2.1.407
Microsoft Word	v. 15.0.4420.1017	v. 16.0.10359.20023
Microsoft Power Point	v. 15.0.4420.1017	v. v. 16.0.10359.20023

Non-Clinical Testing Summary	Design verification activities for functional testing were performed with their respective acceptance criteria to ensure that the proposed modifications do not affect the safety or effectiveness of the device. All testing performed met the established performance specifications. **Testing** The Workmate Claris™ System v1.2 was developed and tested in accordance with the following industry guidance documents and standards: • Off-the-Shelf Software Use in Medical Devices Guidance for Industry and Food and Drug Administration Staff • 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 • EN ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices **Types of Testing Performed** • Software verification testing to ensure the software continues to meet requirements following the proposed modifications • Design validation studies to ensure the installation process for updating the applicable software and firmware components meets requirements and that the system remains compatible with common electrophysiology lab equipment. **Risk Management** • The changes to the Workmate Claris™ System v1.2 were evaluated through review of risk management to ensure no new hazards have been introduced by this change.
Statement of Equivalence	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 demonstrated to be substantially equivalent.