510(k) SUMMARY

Submitter's Name / Contact Person

Timothy J. Kappers, MBA, RAC
Sr. Manager, Regulatory Affairs

OCT - 9 2009

St. Jude Medical, Inc.
Atrial Fibrillation Division
Cooper Run Executive Park
575 Route 73 North, Building D
West Berlin, NJ 08091-9293 (USA)

FDA Registration # 2248049

General Information

Trade Name	EP-WorkMate™ System, Version 4.2
Common / Usual Name	Programmable Diagnostic Computer
Classification Name	DQK, Class II, CFR 21 870.1425
Predicate Device	EP-WorkMate™ (K063277)

Device Description

The EP-WorkMate system is a computer-based electrophysiological recording and monitoring system that is used to capture, display, store, and retrieve surface and intracardiac electrical signals during electrophysiology studies. It consists of a computer, two 21" high-resolution monitors, a multi-channel signal amplifier and filtering system (signal conditioning unit), a catheter junction box, and a laser printer. The system may also be configured with an integrated EP-4 clinical stimulator and touch-screen computer monitor (cleared in K040207).

The EP-WorkMate 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, and transmitted to the amplifier, which amplifies and conditions the signals before they are received by the EP-WorkMate computer for measurement and display.

During the procedure, cardiac signals are acquired and an automated software waveform detector (trigger) performs online recognition of cardiac activation on pre-selected leads. Temporal interval measurements are computed on multiple channels on a beat-by-beat basis and dynamically displayed on the real-time display. Menu-driven

software is utilized for data acquisition and analysis, interval posting, and instant data retrieval with waveform markers and intervals displayed.

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.

Software Description

The EP-WorkMate's system functions are controlled by the system software – signal acquisition, amplification, conditioning and display, electrocardiograph recording and monitoring, case annotation, and data output to external components, storage and retrieval. The menu-driven software is controlled through a user interface with a keyboard or mouse.

Key features of the EP-WorkMate are:

- Dual monitors – real-time and review
- Signal analysis tools
- Real-time interval analysis
- Integrated stimulator
- Activation mapping
- Pace mapping tools
- Fully integrated RF and cryo ablation generator interfaces
- Ablation window
- Holter window
- Mapping window
- Storage and retrieval of study data
- Database query functions
- Post-acquisition data processing
- Full report and printout functions

Hardware Description

The EP-WorkMate consists of a computer, two 21" high-resolution monitors, a multi-channel signal amplifier and filtering system (signal conditioning unit), a catheter junction box, and a laser printer. The system may also be configured with an EP-4 clinical stimulator and touchscreen computer monitor (K040207).

Connections

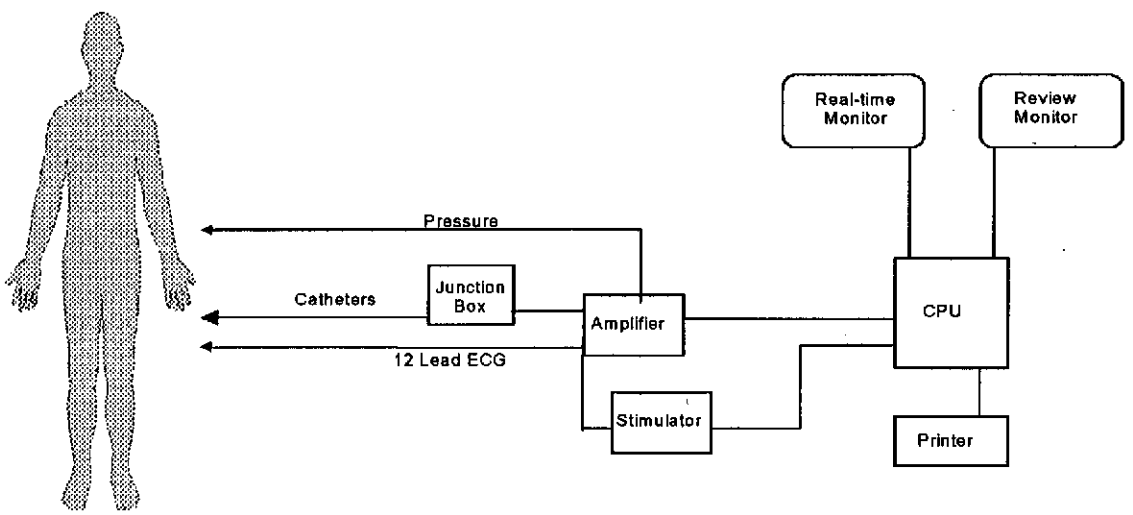
The patient is connected to the EP-WorkMate by a surface ECG cable, intracardiac catheters and optional intravascular pressure transducers. Patient ECG and catheter

cables are connected directly to the electrically isolated junction box, and pressure transducers are connected to the amplifier and signal conditioning unit (SCU) box.

The signal amplifier and signal conditioning unit (SCU) box receives signal inputs from the junction box and marker/pressure interface box. The signals are then amplified, converted from analog to digital, filtered/conditioned and transmitted to the EP-WorkMate computer via Ethernet cabling.

The computer receives inputs from the amplifier/SCU as well as additional data received via standard RS-232 and USB connections from the cardiac stimulator and other external device sources. The computer then transmits data to the EP-WorkMate's real-time and review monitors for display, as directed by user inputs entered through a mouse and/or keyboard computer interface. Digitized case data are also transmitted to the system printer, DVD-R drive, or networked connection. See Figure 1 for a graphical presentation of system interconnections.

Figure 1: EP-WorkMate Interconnection Diagram



Indications for Use

The EP-WorkMate™ System is indicated for use during clinical electrophysiology procedures.

Intended Use

The EP-WorkMate® system with an EP-4 stimulator is intended to be used for diagnostic electrical stimulation of the heart for the purpose of refractory measurements, initiation and termination of tachy-arrhythmias, measurements of electrical conduction, and arrhythmia mapping.

Device Comparison to the Cleared Device

The EP-WorkMate has the same intended use and fundamental scientific technology as the predicate device. All technological characteristics of the EP-WorkMate system are substantially equivalent to the predicate device.

Summary of Non-Clinical Testing

Bench testing was performed to confirm that the changes met design requirements and did not affect the safety or effectiveness of the product.

Summary of Design Control Activities

The development of the EP-WorkMate system was performed in accordance with St. Jude Medical's Quality System requirements, and in compliance with Quality System Regulation design controls requirements documented in 21 CFR 820.30. A Declaration of Conformity with Design Controls is provided in Attachment I.

Conclusion

The EP-WorkMate has the same indications for use, intended use and fundamental scientific technology as the predicate devices. All technological characteristics of the EP-WorkMate are substantially equivalent to the predicate device.

Where operational and performance differences exist between the proposed device and the predicate device, performance testing demonstrated that these differences do not adversely affect the device's safety and effectiveness.

Therefore, St. Jude Medical considers the EP-WorkMate to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

OCT - 9 2009

St. Jude Medical
c/o Mr. Timothy J. Kappers, MBA, RAC
Sr. Manager, Regulatory Affairs
Atrial Fibrillation Division
Cooper Run Executive Park
575 Route 73 North Unit-D
West Berlin, NJ 08091

Re: K092810
Trade/Device Name: EP-WorkMate™ System, Version 4.2
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: September 9, 2009
Received: September 11, 2009

Dear Mr. Kappers:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. A. Hillebrenner

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

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K092810

Device Name: EP-WorkMate™ System, Version 4.2

Indications for Use:

The EP-WorkMate™ System is indicated for use during clinical electrophysiology procedures.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. A. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092810