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510(k) SUMMARY

Submitter's Name/Contact Person

DEC 15 2009

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

FDA Registration # 2248049

General Information

Trade Name	EP-NurseMate™ Remote Review and Charting Station (also referred to as EP-NurseMate™) EP-NurseMate™ with Physio Remote Review and Charting Station with Physiologic Monitoring Module (also referred to as EP-NurseMate™ with Physio Module)
Common/Usual Name	Computer, diagnostic, programmable
Classification Name	DQK, Class II, 21 CFR 870.1425
Predicate Device	NurseMate™ NurseMate with Physio Module™

Device Description

The EP-NurseMate™ and the EP-NurseMate™ with Physio Module, Version 4.2.0, are modifications to the EP-WorkMate™ Recording System. The EP-NurseMate is connected to the EP-WorkMate Recording System for real-time charting, physiologic monitoring, and data analysis during electrophysiology (EP) studies. Expanding the EP-

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WorkMate™ Recording System with the optional EP-NurseMate™ or EP-NurseMate™ with Physio Module creates an additional workstation for a member of the EP team to perform charting (e.g., event titles, medications, and comments) and monitor physiologic data from their own display.

Software Description

The EP-NurseMate™ and the EP-NurseMate™ with Physio Module's functions are controlled by system software. The menu driven software is controlled through a user interface with a touchscreen LCD monitor or keyboard. The EP-NurseMate™ and the EP-NurseMate™ with Physio Module software is a modified version of the EP-WorkMate™ application software. The software was modified using the same Microsoft Visual C++ 6.0 Integrated Development Environment (with Visual Studio Service Pack 6.0A) within which it was originally developed. It is important to note that NurseMate™/EP-NurseMate™ with Physio Module do not control the patient monitor and do not control cardiac stimulation.

Hardware Description

The EP-NurseMate™ hardware consists of a PC, a touchscreen LCD monitor, a keyboard, and a cart.

The EP-NurseMate™ with Physio Module consists of a PC, a touchscreen LCD monitor, a keyboard, a physiologic monitoring device, and a cart.

A graphical presentation of the system interconnections is provided in Figures 1 and 2 of for EP-NurseMate™ and EP-NurseMate™ with Physio, respectively.

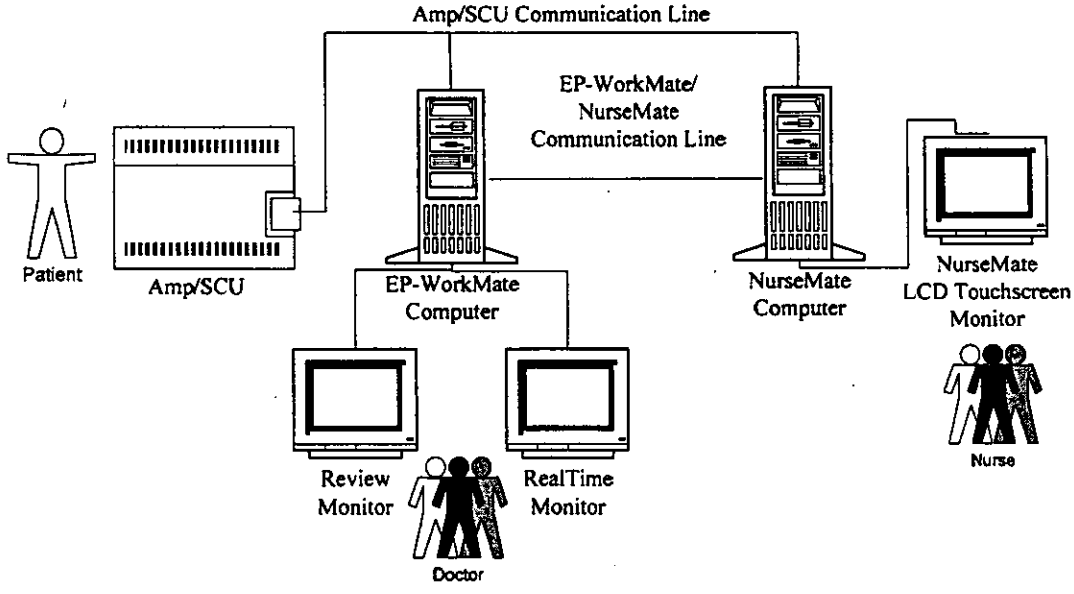

Figure 1 EP-WorkMate™ with NurseMate™ Block Diagram

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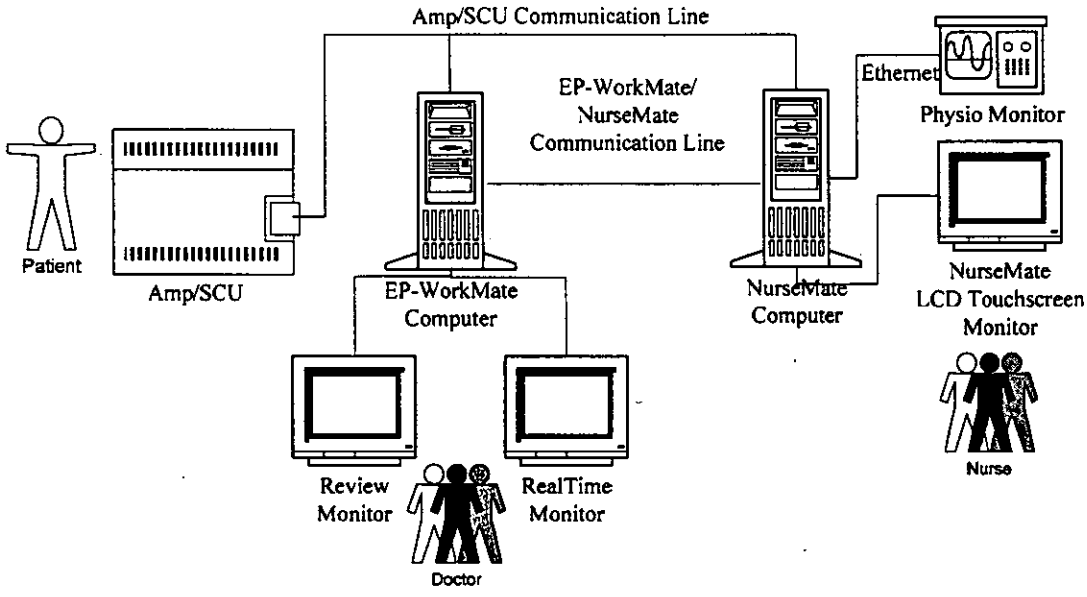

Figure 2: EP-WorkMate® with NurseMate™ with Physio Module Block Diagram

Indications for Use

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

The EP-NurseMate™ with Physio is indicated for use during clinical electrophysiology procedures.

Intended Use

The EP-NurseMate™ is intended to be used as an extension of the EP-WorkMate™ Recording System for the viewing and measurements of cardiac electrograms, and electronic data entry of procedural events during a clinical electrophysiology procedure.

The EP-NurseMate™ with Physio Module is intended to be used as an extension of the EP-WorkMate™ Recording System for the viewing and measurements of cardiac electrograms, receiving vital signs measurements from a patient monitoring unit, and electronic data entry of procedural events during a clinical electrophysiology procedure.

Device Comparison to the Cleared Device

The EP-NurseMate and the EP-NurseMate with Physio Modules have the same indications for use and fundamental scientific technology as the predicate devices. All technological characteristics of the devices are substantially equivalent to the predicate devices.

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Summary of Non-Clinical Testing

Clinical simulation testing was performed to confirm that the changes met design requirements and did not adversely affect the safety or efficacy of the devices.

Summary of Design Control Activities

The development of the EP-NurseMate™ and the EP-NurseMate™ with Physio Module were performed in accordance with St. Jude Medical's Quality System requirements, and in compliance with Quality System Regulation design control requirements documented in 21 CFR 820.30. A Declaration of Conformity with Design Controls is provided in Attachment J.

Conclusion

The EP-NurseMate™ and the EP-NurseMate™ with Physio Module have the same indications for 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-NurseMate™ and the EP-NurseMate with Physio Module 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

DEC 15 2009

St. Jude Medical, Inc.
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo MN 53313

Re: K093583
Trade/Device Name: EP-NurseMate and EP-NurseMate with Physio Module version 4.2
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: December 5, 2009
Received: December 9, 2009

Dear Mr. Job:

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.

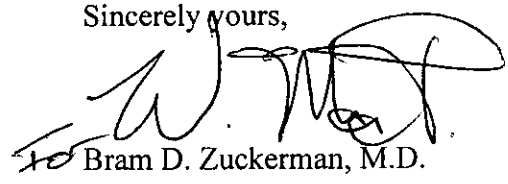
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 (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

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Indications for Use

510(k) Number (if known) K093583

Device Name:
EP-NurseMate™ (EP-NurseMate™ Remote Review and Charting Station)
EP-NurseMate™ with Physio Module (EP-NurseMate™ Remote Review and Charting Station with Physiologic Monitoring Module)

Indications for Use:

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

The EP-NurseMate™ with Physio Module is indicated for use during clinical electrophysiology procedures.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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