smiths medical
bringing technology to life

Smiths Medical
1265 Grey Fox Road
St. Paul, MN 55112
T: 651 633 2556
F: 651 628 7459
www.smiths-medical.com

510(k) Summary

510(k) 141193

JUL 25 2014

DATE PREPARED: 16-JULY-2014

I. GENERAL INFORMATION

Applicant's Name and Address:	Smiths Medical ASD, Inc. 1265 Grey Fox Road St. Paul, MN 55112
Contact Person:	Tom Bliss Sr. Specialist, Regulatory Affairs
Common/Usual Name:	Infusion Safety Management Software
Product Code:	PHC
Proprietary Name:	Medfusion® 4000 Pump Device Specific Reports Software for PharmGuard® Server, Version 2.0
Predicate Device/ 510(k):	K111386, Medfusion® Model 4000 Series Syringe Infusion Pump, PharmGuard® Toolbox 2.0 Medication Safety Software

II. DEVICE DESCRIPTION

The Medfusion® 4000 Pump Device Specific Reports Software, Version 2.0 software is a medical device intended to be used in the analysis of infusion data, provide information used in forming clinical workflow decisions and improve infusion safety. The Medfusion® 4000 Pump Device Specific Reports Software, Version 2.0 is an infusion pump accessory compatible with the PharmGuard® Server, which stores data exported from networked infusion pumps. The Medfusion® 4000 Pump Device Specific Reports Software, Version 2.0 copies data from the PharmGuard® Server databases and uses it to create reports.

The Medfusion® 4000 Pump Device Specific Reports Software, Version 2.0 can be used for transferring, displaying or storing and retrieving historical clinical data, clinical and operational alarm events, fault events, power events, maintenance events, therapy and therapy change events and telemetry events that are generated by the networked infusion pumps and stored in the PharmGuard® Server. It is also intended for near real-time monitoring of infusion pump history. For the purposes of this device "near real-time" is associated with time intervals typically measured in minutes rather than in seconds or in hours.

The Medfusion® 4000 Pump Device Specific Reports Software, Version 2.0 manipulates and re-configures data to present information beyond the discrete data that is displayed on the pumps.

Reports include information on drug compliance, safety events, alarm history, drug program utilization, and pump technical status. Reports can summarize data and reveal trends in these areas by presenting results summarized by such parameters as time of day, facility, drug profile, alarm type and safety events. The information may be presented graphically, in table form and in some cases allows "drill through" to the underlying data used to produce the reports.

The Device Specific Reports Software comprises:

- Instructions for Use and Help Files
- An executable file for launching the application
- A Configuration Tool that provides a user interface to enter, update, and apply the configuration parameters that operate the Data Mart associated with the Medfusion 4000® Device Specific Reports and associated SQL Server databases
- Metadata that is imported into the PharmGuard® Server System and that determines what information within the PharmGuard® Server is available to be output via the Device Specific Report software
- Infrastructure files that interact to facilitate and coordinate the data acquisition, storage, and processing between the PharmGuard® Repository and the Medfusion® 4000 Pump Device Specific Report data mart. The Reporting Infrastructure performs the following major tasks:
    - Extract, Transform, and Load (ETL) data from the PharmGuard Repository into the Reporting Infrastructure data mart.
    - Store device event data in the data mart
    - Process requests for data retrieval for device specific reports

III. DEVICE INTENDED USE

Device Specific Reports provide the user information compiled from data generated by networked devices and stored in the PharmGuard Server. This information may be used to support continuous quality improvement programs. Reports generated from the data can be used to analyze and trend various aspects of the designated infusion pump systems and therapies used.

IV. SUMMARY OF STUDIES

Performance Testing
Smiths Medical performed software validation testing on the Medfusion® 4000 Pump Device Specific Reports Software, Version 2.0

Clinical Studies
Human clinical studies were deemed unnecessary to evaluate the safety or effectiveness of the Medfusion® 4000 Pump Device Specific Reports Software, Version 2.0

Testing Conclusion
All testing met pre-established specifications, and successfully demonstrated that the device performed as intended. The testing results allowed for a conclusion to be made that the Medfusion® Model 4000 Series Syringe Infusion Pump with the Medfusion® 4000 Pump Device Specific Reports Software, Version 2.0 was as safe and effective as the predicate device.

VII. STATEMENT OF EQUIVALENCE

The Medfusion® 4000 Pump Device Specific Reports Software, Version 2.0 is an accessory to the Medfusion® Model 4000 Series Syringe Infusion Pump. The design and use of the Medfusion® 4000 Pump Device Specific Reports Software, Version 2.0 does not affect the device classification, intended use, technological characteristics, or risks associated with the pump. Validation tests confirmed the suitability of the Medfusion® 4000 Pump Device Specific Reports Software, Version 2.0 device for its intended use. The test results did not raise new safety or performance questions, and confirmed that the Medfusion® Model 4000 Series Syringe Infusion Pump with the Medfusion® 4000 Pump Device Specific Reports Software, Version 2.0 accessory is substantially equivalent to the predicate device.

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

July 25, 2014

Thomas Bliss
Senior Regulatory Affairs Specialist
Smiths Medical ASD, Inc.
1265 Grey Fox Road
St. Paul, Minnesota 55112

Re: K141193
Trade/Device Name: Medfusion 4000 Pump Device Specific Reports Software for PharmGuard Server Version 2.0
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: PHC
Dated: May 7, 2014
Received: May 8, 2014

Dear Mr. Bliss:

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" (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 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,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K141193

Device Name:
Medfusion® 4000 Pump Device Specific Reports Software for PharmGuard® Server, Version 2.0

Indications for Use:
Device Specific Reports provide the user information compiled from data generated by networked devices and stored in the PharmGuard Server. This information may be used to support continuous quality improvement programs. Reports generated from the data can be used to analyze and trend various aspects of the designated infusion pump systems and therapies used.

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)

Mary E. Brooks -A
2014.07.17
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