510(k) Summary
(As required by 21CFR 807.92(c))

AUG 2 9 2011

510(k) Number: K111386

Date Prepared 24 August, 2011

Submitter Information

Submitter's Name: Smiths Medical ASD, Inc.
Address: 1265 Grey Fox Road
St. Paul, MN 55112

Establishment Registration: 2183502

Contact Person: James Chapman
Senior Regulatory Affairs Specialist
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Device Information

Trade Name: Medfusion® Model 4000 Syringe Infusion Pump,
PharmGuard® Toolbox 2 Medication Safety Software
PharmGuard® Supported Syringes (PSS)

Common Name: Syringe Infusion Pump, Medication Safety Software
Classification Name: Infusion Pump
Product Code: FRN, MRZ
Regulation: 21 CFR §880.5725

Predicate Device(s)

The predicate devices are the currently marketed Medfusion® Model 3500 Syringe Infusion Pump (K040899), PharmGuard® Toolbox (K042432), ALARIS Medical Systems, Inc. Medley™ Syringe Pump Module (K023264), and the ALARIS Medical Systems Inc. Medley™ System with Medication Management System (K030459).

Device Description

The Medfusion® Model 4000 Syringe Infusion Pump software version 1.1 is a wireless capable electro-mechanical syringe infusion pump.

The PharmGuard® Toolbox 2 Medication Safety Software is designed to accommodate the features and capabilities of the 4000 pump with software version 1.X.

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Intended Use/Indications for Use

The Medfusion® Model 4000 Syringe Infusion Pump is indicated for the following uses:

- In the administration of fluids requiring precisely controlled infusion rates including blood or blood products, lipids, drugs, antibiotics, enteral solutions and other therapeutic fluids.
- By the following delivery routes: arterial, epidural, intravenous, intrathecal, subcutaneous, and enteral.
- By the following delivery modes: continuous, volume/time, mass, body weight, custom dilution, intermittent and bolus.
- In critical care, anesthesia, neonatal and pediatric applications or other healthcare settings where the use of the syringe infusion pump can be monitored or supervised by a clinician.
- Inside the MRI room mounted outside the 150 Gauss line and with shielded magnets of field strength of 1.5 Tesla.

The PharmGuard® Toolbox 2 Medication Safety Software is indicated to provide a vehicle to create and securely upload user-defined configuration parameters, a library of drug names and associated user-defined infusion parameters to Medfusion® Model 4000 Syringe Infusion Pump with software version 1.X. The PharmGuard® Toolbox 2 Medication Safety Software collects and downloads operational, infusion and alarm history events, library usage counts, and PharmGuard® safety events from the Medfusion® Model 4000 Syringe Infusion Pump. It is intended to provide a dataset users can collect and analyze to improve overall processes and lessen the likelihood of operator error when entering infusion parameters into the Medfusion® Model 4000 Syringe Infusion Pump.

The PharmGuard® Supported Syringes is an accessory to the PharmGuard® Toolbox 2 Medication Safety Software that expands the available supported syringes that can be selected when creating user defined configuration parameters using the PharmGuard® Toolbox 2 Medication Safety Software.

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Comparison of Technological Features

Parameter	Medfusion 4000 Syringe Infusion Pump 510(k) K111386	Medfusion 3500 Syringe Infusion Pump 510(k) K040899	ALARIS Medley™ Syringe Pump Module 510(k) K023264
System Features			
Plunger Force Sensing	Yes	Yes	Unknown
MRI Compatibility	≤ 150 Gauss/1.5 Tesla	≤ 150 Gauss/1.5 Tesla	Unknown
Fluid Resistance	Level IPX 3	Level IPX 3	Level IPX 1
Fast Occlusion Detection	Yes	Yes	Yes
Minimum Flow Rate	0.01 mL/hr	0.01 mL/hr	0.1 mL/hr
Maximum Flow Rate	1130 mL/hr	1130 mL/hr	999 mL/hr
Wireless Communications Capabilities	Yes	No	Yes
Programming Functions			
Continuous Mode	Yes	Yes	Yes
Volume/Time Mode	Yes	Yes	Yes
Dose/Time Mode	Yes	Yes	Yes
Mass Mode	Yes	Yes	No
Body Weight Mode	Yes	Yes	Yes
Body Surface Area Mode	Yes	Yes	Yes
Intermittent Mode	Yes	Yes	Yes
Dose/Kg/Time Mode	Yes	Yes	No
Bolus	Yes	Yes	Yes
Alarms			
KVO Alarm	Yes	Yes	Yes
Infusion Complete Alarm	Yes	Yes	Yes
Near Empty Alarm	Yes	Yes	No
Empty Alarm	Yes	Yes	Yes
Invalid Syringe Size Alarm	Yes	Yes	No
Syringe Not in Place Alarm	Yes	Yes	Yes
Pressure Increasing Alarm	Yes	Yes	No
Force Occlusion Alarm	Yes	Yes	Yes
Battery Failed Alarm	Yes	Yes	Yes
Low Battery Alarm	Yes	Yes	Yes
Depleted Battery Alarm	Yes	Yes	Yes

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Summary of Non-Clinical Testing

The non-clinical testing included assessment of the physical properties of the Medfusion® 4000 Syringe Infusion Pump and PharmGuard® Toolbox 2 Medication Safety Software and their ability to achieve their intended use. Bench testing of the Medfusion® 4000 Syringe Infusion Pump confirmed the suitability of the device for its intended use. The following physical tests were performed:

- Accuracy Testing with All Supported Syringes
- Impact Testing
- Environmental Testing
- Accuracy Testing at Simulated Altitude
- Magnetic Resonance Testing in Accordance with ASTM-F2052
- Moisture Ingress Testing
- Chemical Compatibility Testing
- Power Management
- Fault Condition Testing
- Sensor Testing
- Software Validation Testing
- Drug Compatibility Testing
- Mechanical and Electrical Safety Testing in Accordance with EN IEC 60601-1 and EN IEC 60601-2-24
- EMC Testing in Accordance with EN IEC 60601-2
- Radio Frequency Interference Testing
- Product Reliability Testing

In addition to the above, Human Factors Engineering validation studies were conducted in a simulated use environment to verify product understanding and pump programming and operation. Human Factors Engineering testing demonstrated that the Medfusion® Model 4000 Syringe Infusion Pump performed as designed and is safe and effective for its intended use.

A biocompatibility assessment of the device was also performed. The purpose of the biocompatibility assessment was to ensure that biocompatibility had been established for the Medfusion® Model 4000 pump. The device is biocompatible based on the similarity of the materials of construction to other devices currently marketed by Smiths Medical ASD, Inc.

Summary of Clinical Testing

Human clinical studies were deemed not necessary to evaluate the safety or effectiveness of the Medfusion® Model 4000 Syringe Infusion Pump and PharmGuard® Toolbox 2 Medication Safety Software.

Statement of Equivalence

The Medfusion® Model 4000 Syringe Infusion Pump and PharmGuard® Toolbox 2 Medication Safety Software are substantially equivalent to the currently marketed Medfusion® Model 3500 Syringe Infusion Pump, PharmGuard® Toolbox, ALARIS Medical Systems, Inc. Medley™ Syringe Pump Module, and the ALARIS Medical Systems Inc. Medley™ System with Medication Management System based on a comparison of the indications for use and the technological characteristics of the devices.

510(k) Summary
(As required by 21CFR 807.92(c))

Conclusion

The Medfusion® Model 4000 Syringe Infusion Pump and PharmGuard® Toolbox 2 Medication Safety Software are substantially equivalent to the currently marketed Medfusion® Model 3500 Syringe Infusion Pump, PharmGuard® Toolbox, ALARIS Medical Systems, Inc. Medley™ Syringe Pump Module, and the ALARIS Medical Systems Inc. Medley™ System with Medication Management System based on the technological characteristics of the devices. Bench tests confirmed the suitability of the devices for their intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. James Chapman
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St. Paul, Minnesota 55112

AUG 29 2011

Re: K111386
Trade/Device Name: Medfusion® Model 4000 Syringe Infusion System, PharmGuard® Toolbox 2 Medication Safety Software, PharmGuard® Supported Syringes
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: FRN, MRZ
Dated: August 8, 2011
Received: August 10, 2011

Dear Mr. Chapman:

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 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

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SMITHS MEDICAL ASD, INC.
510(k) Premarket Notification

Indications for Use Statement

510(k) Number: K111386

Device Name: PharmGuard® Supported Syringes

Indications for Use:

"The PharmGuard® Supported Syringes is an accessory to the PharmGuard® Toolbox 2 Medication Safety Software that expands the available supported syringes that can be selected when creating user defined configuration parameters using the PharmGuard® Toolbox 2 Medication Safety Software."

Prescription Use (Per 21 CFR 801 .109)	X	AND/OR	Over-The Counter Use (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)

8/25/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111386

SMITHS MEDICAL ASD, INC.
510(k) Premarket Notification

Indications for Use Statement

510(k) Number: K111386

Device Name: Medfusion® Model 4000 Syringe Infusion Pump

Indications for Use:

"The Medfusion® Model 4000 Syringe Infusion Pump is indicated for the following uses:

- In the administration of fluids requiring precisely controlled infusion rates including blood or blood products, lipids, drugs, antibiotics, Enteral solutions and other therapeutic fluids.
- By the following delivery routes: arterial, epidural, intravenous, intrathecal, subcutaneous, and enteral.
- By the following delivery modes: continuous, volume/time, mass, body weight, custom dilution, intermittent and bolus.
- In critical care, anesthesia, neonatal and pediatric applications or other healthcare settings where the use of the syringe infusion pump can be monitored or supervised by a clinician.
- Inside the MRI room mounted outside the 150 Gauss line and with shielded magnets of field strength of 1.5 Tesla.

Prescription Use (Per 21 CFR 801 .109)	X	AND/OR	Over-The Counter Use (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

8/26/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111386

SMITHS MEDICAL ASD, INC.
510(k) Premarket Notification

Indications for Use Statement

510(k) Number: K111386

Device Name: PharmGuard® Toolbox 2 Medication Safety Software

Indications for Use:

"The PharmGuard® Toolbox 2 Medication Safety Software is indicated to provide a vehicle to create and securely upload user-defined configuration parameters, a library of drug names and associated user-defined infusion parameters to Medfusion® Model 4000 Syringe Infusion Pump with software version V1.0 or higher. The PharmGuard® Toolbox 2 Medication Safety Software collects and downloads operational, infusion and alarm history events, library usage counts, and PharmGuard® safety events from the Medfusion® Pump. It is intended to provide a dataset users can collect and analyze to improve overall processes and lessen the likelihood of operator error when entering infusion parameters into the Medfusion® Pump."

Prescription Use (Per 21 CFR 801 .109)	X	AND/OR	Over-The Counter Use (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

8/25/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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