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

510(k) Number: K091181

Date Prepared 20 April 2009, Updated 11 June, 2009

Submitter Information

JUN 12 2009

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

Establishment Registration: 2183502

Contact Person: James Chapman
Sr. Regulatory Affairs Associate
Phone: (651) 628-7611
Fax: (651) 628-7457

Device Information

Trade Name: Lockbox
Common Name: Lockbox for use with Medfusion™ 3000 Series Pumps
Classification Name:
Product Code: MRZ
Regulation: 21 CFR §880.5725

Predicate Device(s)

The predicate devices are the currently marketed LockBox for use with the CADD®-Solis Ambulatory Infusion Pump (K080743) and LockBox with Syringe Holder (K942161).

Device Description

The Lockbox is an accessory to the Medfusion™ 3000 Series Syringe Pump. It is a lockable, plastic enclosure for the pump when the pump is loaded with a commercially available syringe containing medication. The Lockbox may be attached to an IV pole with the Pole Mount Bracket or with modification to a horizontal square rail.

Intended Use/Indications for Use

The Lockbox is intended to hold a Medfusion™ 3000 Series Syringe Pump and provide reasonably secure access to the medication syringe contained within.

K091181

510(k) Summary

Summary of Non-Clinical Testing

The non-clinical testing included assessment of the physical properties of the Lockbox and its ability to achieve its intended use. Bench testing of the Lockbox confirmed the suitability of the device for its intended use. The following physical tests were performed:

Bench Testing
Usability Studies

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 device. The device is biocompatible based on the similarity of the materials of construction to other devices currently marketed by Smiths Medical MD, Inc.

Summary of Clinical Testing

Human clinical studies were deemed not necessary to evaluate the safety or effectiveness of the Lockbox.

Statement of Equivalence

The Lockbox for Medfusion™ 3000 Series Pumps is substantially equivalent to the currently marketed LockBox for use with the CADD®-Solis Ambulatory Infusion Pump and LockBox with Syringe Holder based on a comparison of the indications for use and the technological characteristics of the device.

Conclusion

The Lockbox for use with Medfusion™ 3000 Series Pumps is substantially equivalent to the currently marketed LockBox for use with the CADD®-Solis Ambulatory Infusion Pump and LockBox with Syringe Holder based on the technological characteristics of the devices. Bench tests confirmed the suitability of the device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2009

Mr. James Chapman
Senior Regulatory Affairs Associate
Smiths Medical MD, Incorporated
1265 Grey Fox Road
Sait Paul, Minnesota 55112

Re: K091181
Trade/Device Name: Lockbox for Medfusion™ 3000 Series Pumps
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MRZ
Dated: April 20, 2009
Received: April 23, 2009

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.

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/Centers_Offices/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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

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

Indications for Use Statement

510(k) Number: K091181

Device Name: Lockbox for Medfusion™ 3000 Series Pumps

Indications for Use:

"The Lockbox is intended to hold a Medfusion™ 3000 Series Pump and provide reasonably secure access to the medication syringe contained within."

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

(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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091181