K082783

510(k) Premarket Notification
510(k) Summary

DEC 17 2008

GENERAL INFORMATION

Applicant's Name and Address:	Smiths Medical MD, Inc. 1265 Grey Fox Road St. Paul, MN 55112
Contact Person:	Phil Neururer Sr. Regulatory Affairs Specialist
Common/Usual Name:	Pump Communications System
Proprietary Name:	CADD®-Solis Medication Safety Software
Classification Name:	21 CFR 880.5725, Accessories, Pump, Infusion
Product Code	MRZ
Equivalence Device Comparison:	CADD®-Solis Medication Safety Software, and CADD-Sentry *Pro*™ Medication Safety Software

II. DEVICE DESCRIPTION

CADD®-Solis Medication Safety Software

The Smiths Medical MD, Inc. CADD®-Solis Medication Safety Software, a software program that operates on commercially available personal computers or similar hardware platforms such as tablets, is designed for pump programming of the CADD®-Solis Ambulatory Infusion Pump and CADD-Prizm® PCS II Ambulatory Infusion Pump (software revision H or higher) through a therapy-based protocol database defined by the user. The CADD®-Solis Medication Safety Software consists of an Administrator and a Point-of-Care (POC) software module that employs serial communications to send and receive pump information. Both modules are compatible with barcode scanners (or similar input devices) through various PC connections. Barcode format is determined by the user; but is limited to 20 alphanumerical characters. The CADD®-Solis Medication Safety Software does not allow duplicative Drug, Protocol or User identification entries.

The CADD®-Solis Medication Safety Software – Administrator module allows the user to create, edit, and save therapy-based protocols and pump settings within user-defined protocol libraries. The Administrator user determines POC user access and library editing capabilities. Other Administrator module features include barcode printing, reports, and sending and receiving pump information.

The CADD®-Solis Medication Safety Software – Point of Care module allows the user to download therapy based protocols to the CADD®-Solis Ambulatory Infusion Pump and CADD-Prizm® PCS II Ambulatory Infusion Pump (software revision H or higher) and send and receive pump settings via serial communication. Additional features include storing and printing pump program settings and reports, verifying pump settings to established protocols and viewing history logs in the easier view of a PC monitor.

III. INTENDED USE OF THE DEVICE

CADD®-Solis Medication Safety Software - Administrator

The CADD®-Solis Medication Safety Software - Administrator allows use of a computer to create therapy based protocol libraries to be used with the CADD®-Solis Ambulatory Infusion Pump or CADD-Prizm® PCS II Ambulatory Infusion Pump (software revision H or higher).

CADD®-Solis Medication Safety Software – Point of Care

The CADD®-Solis Medication Safety Software – Point of Care allows use of a computer to send therapy-based protocols developed by the CADD®-Solis Medication Safety Software – Administrator to the CADD®-Solis Ambulatory Infusion Pump and CADD-Prizm® PCS II Ambulatory Infusion Pump (software revision H or higher).

IV. DEVICE COMPARISON

CADD®-Solis Medication Safety Software

The CADD®-Solis Medication Safety Software was compared to and found to be substantially equivalent to the following commercially available predicate devices: CADD®-Solis Medication Safety Software, and CADD-Sentry *Pro*™ Medication Safety Software.

V. SUMMARY OF STUDIES

A. Functional Testing

Test plans associated with software validation, verification of software controlled programming functions and pump operation were performed.

B. Clinical Studies

Human clinical studies were deemed not necessary to evaluate the safety or effectiveness of the CADD®-Solis Medication Safety Software.

C. Conclusions Drawn from the Studies

Based upon the information provided, the CADD®-Solis Medication Safety Software is safe, effective and performs to established specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Phil Neururer
Senior Regulatory Affairs Specialist
Smiths Medical MD, Incorporated
1265 Grey Fox Road
St. Paul, Minnesota 55112

DEC 17 2008

Re: K082783
Trade/Device Name: CADD® - Solis Medication Safety Software - Administrator
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MRZ
Dated: December 11, 2008
Received: December 12, 2008

Dear Mr. Neururer:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Chiu Lin, Ph.D.
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
CADD®-Solis Medication Safety Software

Indications for Use

510(k) Number: _____

Device Name: **CADD®-Solis Medication Safety Software – Administrator**

Indications for Use:

"The CADD®-Solis Medication Safety Software - Administrator allows use of a computer to create therapy based protocol libraries to be used with the CADD®-Solis Ambulatory Infusion Pump or CADD-Prizm® PCS II Ambulatory Infusion Pump (software revision H or higher)."

Prescription Use ___X___ OR Over-The Counter Use _____ Per 21 CFR 801.109

Device Name: **CADD®-Solis Medication Safety Software – Point of Care**

Indications for Use:

"The CADD®-Solis Medication Safety Software – Point of Care allows use of a computer to send therapy-based protocols developed by the CADD®-Solis Medication Safety Software – Administrator to the CADD®-Solis Ambulatory Infusion Pump and CADD-Prizm® PCS II Ambulatory Infusion Pump (software revision H or higher)."

Prescription Use ___X___ OR Over-The Counter Use _____ Per 21 CFR 801.109

(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: K982783