510(k) Summary

MAR - 7 2005

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:	Ambulatory Infusion Pump Pump Communications System
Proprietary Name:	CADD®-Solis Ambulatory Infusion Pump CADD®-Solis Medication Safety Software
Equivalence Device Comparison:	CADD-Prizm® PCS II Model 6101 Ambulatory Infusion System CADD-Sentry Pro® Medication Safety

II. DEVICE DESCRIPTION

CADD®-Solis Ambulatory Infusion Pump

The CADD®-Solis ambulatory infusion pump ("Solis Pump") provides measured drug therapy to patients in the hospital setting. The pump can be programmed to deliver medication at a continuous rate, patient controlled analgesia (PCA), clinician bolus, continuous rate plus PCA, and continuous rate plus clinician bolus.

CADD®-Solis Medication Safety Software – Administrator

The Smiths Medical MD, Inc. CADD®-Solis Medication Safety Software – Administrator ("Solis Safety Software – Administrator"), a server based software program that operates on commercially available computers, is designed to establish user defined therapy based protocols for use by the Solis Pump or for use by use CADD®-Solis Medication Safety Software – Point of Care (POC) to program the CADD-Prizm® PCS II Ambulatory Infusion Pump (software revision H or higher). The Solis Safety Software – Administrator does not allow duplicative Drug, Protocol or User identification entries.

k072144

III. INTENDED USE OF THE DEVICE

CADD®-Solis Ambulatory Infusion Pump

The CADD®-Solis ambulatory infusion pump is indicated for intravenous, intra-arterial, subcutaneous, intraperitoneal, in close proximity to nerves, into an intraoperative site (soft tissue, body cavity/surgical wound site), epidural space, or subarachnoid space infusion, patient controlled PCA doses, or both.

CADD®-Solis Medication Safety Software – Administrator

The CADD®-Solis Medication Safety Software – Administrator allows you to establish a therapy-based protocol library that will be used by the CADD®-Solis Ambulatory Infusion Pump or by the CADD®-Solis Medication Safety Software – Point of Care to program the CADD-Prizm® PCS II Ambulatory Infusion Pump (software revision H or higher).

V. SUMMARY OF STUDIES

A. Functional Testing

The Solis Pump and Solis Safety Software – Administrator were subjected to verification and validation testing. The verification and validation testing performed demonstrate the devices function as intended and perform to specification.

B. Clinical Studies

Human clinical studies were deemed not necessary to evaluate the safety or effectiveness of the CADD-Sentry *Pro*™ Medication Safety Software.

C. Conclusions Drawn from the Studies

Based upon the information provided, the CADD-Sentry *Pro*™ Medication Safety Software is safe, effective and performs to established specifications.

K072144

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 7 2008

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

Re: K072144
Trade/Device Name: CADD®-Solis Ambulatory Infusion Pump
CADD®-Solis Medication Safety Software - Administrator
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEA
Dated: February 20, 2008
Received: February 21, 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 Ambulatory Infusion Pump
CADD®-Solis Medication Safety Software

Indications for Use

510(k) Number: K072144

Device Name: **CADD®-Solis Ambulatory Infusion Pump**

Indications for Use:

"The CADD®-Solis ambulatory infusion pump is indicated for intravenous, intra-arterial, subcutaneous, intraperitoneal, in close proximity to nerves, into an intraoperative site (soft tissue, body cavity/surgical wound site), epidural space, or subarachnoid space infusion. The pump is intended for therapies that require a continuous rate of infusion, patient-controlled demand doses, or both (such as patient-controlled analgesia)."

Prescription Use ___X___ OR Over-The Counter Use _____Per 21 CFR 801.109)

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

Indications for Use:

"The CADD®-Solis Medication Safety Software consists of the Administrator and the Point of Care software applications. This software allows you to create a set of standard pump Protocols to be used with the CADD®-Solis Ambulatory Infusion Pump and CADD-Prizm® PCS II Ambulatory Infusion Pump. The Point of Care software application is used for the CADD-Prizm® PCS II Ambulatory Infusion pump (with software revision H or higher) only."

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)

Anthony D. Watson
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072144