510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
CADD-MS™ 3 Ambulatory Infusion Pump
June 13, 2005

K051568

NOV 17 2005

GENERAL INFORMATION

Applicant's Name and Address:	Smiths Medical MD, Inc. 1265 Grey Fox Road St. Paul, MN 55112
Contact Person:	Melanie Hess Regulatory and Clinical Affairs Associate
Common/Usual Name:	Ambulatory Syringe Pump
Proprietary Name:	CADD-MS™ 3 Ambulatory Infusion Pump
Equivalence Device Comparison:	CADD-Micro® Ambulatory Infusion Pump

II. DEVICE DESCRIPTION

The Smiths Medical MD, Inc. CADD-MS™ 3 Ambulatory Infusion Pump, a microprocessor based electronic syringe pump with a 3-ml cartridge reservoir, is designed for low volume syringe-based infusion therapy allowing continuous, automatic dose and demand dose delivery profiles for subcutaneous, intravenous, epidural and intrathecal delivery.

The pump operates on one (1) AAA alkaline battery. The user-interface of hardware features include a backlit liquid crystal display, 4-key front keypad, separate bolus button, audible or vibratory alarm, battery cap and cartridge cap. The pump is waterproof and features a cartridge sensor and downstream occlusion sensor.

Based on user code-entry and an internal real-time clock, a user will be able to program multiple basal (continuous), bolus (demand) dosing and automatic dosing delivery profiles within programmed maximum limits.

The pump accommodates the Smiths Medical MD, Inc. 3ml cartridge reservoir.

III. INTENDED USE OF THE DEVICE

The CADD-MS™ 3 is a syringe infusion pump designed for subcutaneous, intravenous, intrathecal and epidural delivery of medication.

The Smiths Medical MD, Inc. 3ml Cartridge is designed for use with the CADD-MS™ 3 for delivering medication.

IV. DEVICE COMPARISON

The CADD-MS™ 3 Ambulatory Infusion Pump was compared to and found to be substantially equivalent to the following commercially available predicate device: CADD-Micro® Ambulatory Infusion Pump.

The CADD-MS™ 3 Ambulatory Infusion Pump is substantially equivalent to the CADD-Micro® Ambulatory Infusion Pump with respect to indications for use and performance features

V. SUMMARY OF STUDIES

A. Functional Testing

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

Biocompatibility testing for the 3-ml Cartridge was performed and found to be biocompatible.

B. Clinical Studies

Human clinical studies were not deemed necessary to evaluate the safety or effectiveness of the CADD-MS™ 3 Ambulatory Infusion Pump.

C. Conclusions Drawn from the Studies

Based upon the information provided through verification and validation test reports, the CADD-MS™ 3 Ambulatory Infusion Pump 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

NOV 17 2005

Ms. Melanie Hess
Regulatory and Clinical Affairs Associate
Smith Medical MD, Incorporated
1265 Grey Fox Road
St. Paul, Minnesota 55112

Re: K051568
Trade/Device Name: CADD-MS™ 3 Ambulatory Infusion Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: October 31, 2005
Received: November 1, 2005

Dear Ms. Hess:

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) 276-0120. 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 (301) 443-6597 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.
Indications for Use Statement
510(k) Number: K051568

Device Name: CADD-MS™ 3 Ambulatory Infusion Pump

Indications for Use:

"The CADD-MS™ 3 Ambulatory Infusion Pump is designed for subcutaneous, intravenous, epidural and intrathecal infusion of medication."

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

Device Name: Smiths Medical MD, Inc. 3-ml Cartridge Reservoir

Indications for Use:

"The Smiths Medical MD, Inc. 3-ml Cartridge Reservoir is designed for use with the CADD-MS™ 3 for delivering medication."

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 K051568