K130394

DEC - 9 2013

510(k) Summary

DATE PREPARED: December 3, 2013

I. GENERAL INFORMATION

Applicant's Name and Address:	Smiths Medical ASD, Inc. 1265 Grey Fox Road St. Paul, MN 55112
Contact Person:	Paula Cordero Sr. Manager, Global Regulatory Affairs
Common/Usual Name:	1) Ambulatory Infusion Pump 2) Pump Communications System
Proprietary Name:	1) CADD®-Solis Ambulatory Infusion Pump, Model 2110, Version 3.0 2) CADD™-Solis Medication Safety Software, Version 3.1
Equivalence Device Comparison:	1) CADD®-Solis Ambulatory Infusion Pump, Model 2100 or Model 2110, Version 1.0 2) CADD®-Solis VIP Ambulatory Infusion Pump, Model 2120, Version 2.0 3) CADD™-Solis Medication Safety Software Version 1.2 4) CADD™-Solis Medication Safety Software Version 2.0

II. DEVICE DESCRIPTION

CADD®-Solis Ambulatory Infusion Pump, Model 2110, Version 3.0

The CADD®-Solis Ambulatory Infusion Pump, Model 2110, Version 3.0 ("CADD®-Solis Version 3.0 Pump") has a microprocessor and linear peristaltic pumping mechanism, similar in design to the Smiths Medical ASD, Inc. CADD®-Solis Ambulatory Infusion Pump, Version 1.0 (K072144) and CADD®-Solis VIP Ambulatory Infusion Pump, Version 2.0 (K111275). The user activates CADD®-Solis Version 3.0 Pump via a color LCD screen and keypad user interface. Commands are issued to the microprocessor by activating the user interface. Microprocessor actions are controlled by a program, which is contained in the pump's memory.

The CADD®-Solis Version 3.0 Pump consists of components, such as the user interface, sensors, communication ports, power ports, structural (housing) components, electronics, pumping mechanism, watchdog timer, pump battery and circuitry, real time clock, on-board memory, and pump log. The CADD®-Solis Version 3.0 Pump exterior surface components include the pump housing, LCD lens, labels, and keypad, and the materials of construction for these components are widely used in the medical industry. The CADD®-Solis Version 3.0 Pump is designed to be used with a CADD® Infusion Disposable, such as Medication Cassette Reservoir.

CADD™-Solis Medication Safety Software Version 3.1

The CADD™-Solis Medication Safety Software System consists of the Administrator and the Point of Care software applications. This software allows the user 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).

The CADD™-Solis Medication Safety Software System allows the user to:

- Create a protocol library on a server or on a PC.
- Create multiple protocol libraries within the database. Each protocol library can be designated and named for a particular area of each facility.
- Create multiple pump protocols within each protocol library.
- Designate authorized users for each protocol library.
- Program a pump with a therapy-based set of protocols.

The CADD™-Solis Medication Safety Software System can be used in various system configurations, including:

- The protocol library database can be located on a server with one or more Administrator PCs and one or more Point of Care PCs distributed on the network throughout the facility.
- The protocol library database can be located on the Administrator PC and one or more Point of Care PCs distributed over the network throughout the facility.
- The Point of Care PC can be located separately from a network and the protocol libraries can be imported using portable media.

III. DEVICE INTENDED USE

CADD®-Solis Ambulatory Infusion Pump, Model 2110, Version 3.0

The CADD®-Solis Version 3.0 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, and/or an intermittent bolus, and/or with patient-controlled demand doses.

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 VIP Ambulatory Infusion Pump, 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. SUMMARY OF STUDIES

Performance Testing

Smiths Medical performed design verification and software validation testing on the CADD®-Solis Version 3.0 Pump. Software validation testing was performed on the CADD™ Solis Medication Safety Software—Administrator and CADD™ Solis Medication Safety Software—Point of Care. Human-factors engineering studies were also completed.

Clinical Studies

Human clinical studies were deemed unnecessary to evaluate the safety or effectiveness of the CADD®-Solis Version 3.0 Pump, CADD™ Solis Medication Safety Software—Administrator and POC.

Testing Conclusion

All testing met pre-established specifications, and successfully demonstrated that the devices performed as intended. The testing results allowed for a conclusion to be made that the CADD®-Solis Version 3.0 Pump, and CADD™ Solis Medication Safety Software—Administrator and POC were as safe and effective as the predicate devices.

VII. STATEMENT OF EQUIVALENCE

The CADD®-Solis Version 3.0 Pump, and CADD™ Solis Medication Safety Software—Administrator and POC are substantially equivalent to the predicate devices, based on comparisons of the device classifications, intended use, and technological characteristics. Verification and validation tests confirmed the suitability of the devices for their intended uses. The test results did not raise new safety or performance questions, and confirmed that the CADD®-Solis Version 3.0 Pump, and CADD™ Solis Medication Safety Software—Administrator and POC devices are substantially equivalent to the predicate devices.

V. Subject and Predicate Device Comparison Tables

CADD®-Solis Version 3.0, CADD®-Solis VIP Version 1.2, and CADD®-Solis Version 1.0 Pump Comparison Table[1]

Characteristic	Device		
	Subject Device CADD®-Solis Version 3.0 Pump	**Predicate Device CADD®-Solis VIP Version 1.2 Pump**	**Predicate Device CADD®-Solis Version 1.0 Pump**
General Information			
Manufacturer	Smiths Medical ASD, Inc.	Smiths Medical ASD, Inc.	Smiths Medical ASD, Inc.
510(k) notification number and substantial equivalence determination date	K130394, pending	K111275, February 1, 2013	K072144, March 7, 2008
Pump model number	2110	2120	2100 or 2110
Pump firmware version	3.0	1.2	1.0
Product description	The CADD®-Solis Ambulatory Infusion Pump, Model 2110, Version 3.0, provides measured drug therapy to patients in hospital or outpatient settings. The pump can be programmed with a protocol configuration consisting of a therapy, qualifier, and drug. Medication is delivered at a constant rate, and/or with a clinician bolus, and/or with a patient dose, and/or with programmed intermittent boluses.	The CADD®-Solis VIP (variable infusion profile) Ambulatory Infusion Pump, Model 2120, provides measured drug therapy to patients in hospital, outpatient and homecare settings. The pump can be programmed with a pump protocol configuration consisting of a therapy, qualifier, and drug. The pump can deliver medication via patient controlled analgesia (PCA), continuous, intermittent, variable stepped rate, and tapered infusions.	The CADD®-Solis Ambulatory Infusion Pump, Model 2100 or 2110, Version 1.0, provides measured drug therapy to patients in hospital or outpatient settings. The pump can be programmed with a protocol configuration consisting of a therapy, qualifier, and drug. Medication is delivered at a constant rate, and/or with an intermittent bolus, and/or with a patient dose.

[1] The CADD®-Solis Version 2.0 Pump is marketed solely outside of the United States at this time.

Characteristic	Device		
	Subject Device CADD®-Solis Version 3.0 Pump	**Predicate Device CADD®-Solis VIP Version 1.2 Pump**	**Predicate Device CADD®-Solis Version 1.0 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, and/or an intermittent bolus, and/or with patient-controlled demand doses.	The CADD®-Solis VIP Ambulatory Infusion Pump is indicated for intravenous, intra-arterial, subcutaneous, intraperitoneal, perineural, surgical site, epidural space, or subarachnoid space infusion. **PCA** (patient-controlled analgesia) delivery is used for therapies that require a continuous rate of infusion, patient-controlled demand doses, or both, such as patient-controlled analgesia. **Continuous** delivery allows the infusion of drug/fluid at a constant, programmed rate. **Intermittent** delivery allows the infusion of a specific volume of drug/fluid at a regular, programmed interval. **Step** delivery allows an incremental increase in infusion rate to a specified maximum infusion rate for a specified total infusion volume. **Taper** delivery allows a plateau rate of infusion with the option of tapering at the beginning and/or end and has a programmable KVO rate at the end of the infusion.	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).
System Features			
Pump type/principle of operation	Linear peristaltic	Linear peristaltic	Linear peristaltic
Materials of construction—Pump housing	Same for subject and predicate CADD®-Solis Pumps	Same for subject and predicate CADD®-Solis Pumps	Same for subject and predicate CADD®-Solis Pumps

Characteristic	Device		
	Subject Device CADD®-Solis Version 3.0 Pump	**Predicate Device CADD®-Solis VIP Version 1.2 Pump**	**Predicate Device CADD®-Solis Version 1.0 Pump**
Display	Color display with 320 x 320 pixels	Color display with 320 x 320 pixels	Color display with 320 x 320 pixels
Available with gray keypad (denoting general use)	Yes	Yes	Yes
Available with yellow keypad (denoting epidural use)	Yes	No	Yes
Remote dose cord supplied with device	Yes	No	Yes
Power requirements	4 ("AA") batteries AC adapter Rechargeable battery pack	4 ("AA") batteries AC adapter Rechargeable battery pack	4 ("AA") batteries AC adapter Rechargeable battery pack
Printing capabilities	No	No	No
Remote communications capabilities	No	No	No
USB port	Yes	Yes	Yes
Accessories			
AC adapter	Yes	Yes	Yes
AC power cord	Yes	Yes	Yes
Remote dose cord	Yes	No	Yes
Rechargeable power pack	Yes	Yes	Yes
Polemount adapter	Yes	Yes	Yes
Carrying pouch	Yes	Yes	Yes
Lockbox	Yes	Yes	Yes
Medication cassette reservoir	Yes	Yes	Yes
Administration Set	Yes	Yes	Yes
Extension Set	Yes	Yes	Yes
Programming Functions			
Intermittent (programmed intermittent bolus)	Yes	Yes	No
Continuous infusion	Yes	Yes	Yes
Continuous infusion with bolus (PCA)	Yes	Yes	Yes

Characteristic	Device		
	Subject Device CADD®-Solis Version 3.0 Pump	**Predicate Device CADD®-Solis VIP Version 1.2 Pump**	**Predicate Device CADD®-Solis Version 1.0 Pump**
Step	No	Yes	No
Taper	No	Yes	No
Security	Yes	Yes	Yes
Demand dose lockout	Yes	Yes	Yes
Delivery limit	Yes	Yes	Yes
Programmable titration limits	Yes	Yes	Yes
Titration feature available while running	Yes	Yes	Yes
Programmable maximum rate	Yes	Yes	Yes
Cassette/disposable type supported	High flow and standard flow disposables	High flow and standard flow disposables	Standard flow disposables only
Epidural mode	Yes	Yes	Yes
Alarms			
Low battery	Yes	Yes	Yes
Depleted battery	Yes	Yes	Yes
External power source low	Yes	Yes	Yes
No battery alert	Yes	Yes	Yes
Pump in stop mode	Yes	Yes	Yes
High pressure	Yes	Yes	Yes
Power up fault	Yes	Yes	Yes
Low volume in medication reservoir	Yes	Yes	Yes
Cassette detachment	Yes	Yes	Yes
Upstream occlusion	Yes	Yes	Yes
Air-in-line	Yes	Yes	Yes
Key stuck	Yes	Yes	Yes
Infusion Specifications			
Reservoir volume	1 to 9999 mL	1 to 9999 mL	1 to 9999 mL
Minimum continuous delivery rate	0 mL/hr	0 mL/hr	0 mL/hr

Characteristic	Device		
	Subject Device CADD®-Solis Version 3.0 Pump	**Predicate Device CADD®-Solis VIP Version 1.2 Pump**	**Predicate Device CADD®-Solis Version 1.0 Pump**
Maximum continuous delivery rate	100 mL/hr	100 mL/hr in PCA mode 500 mL/hr in Continuous, Intermittent, Taper, Step modes	30 mL/hr
Maximum bolus delivery rate	250mL with standard flow disposable 500mL with high flow disposable	250mL with standard flow disposable in PCA mode	175mL with standard flow disposable
Maximum patient bolus	50 mL	50 mL	20 mL
Maximum clinician bolus	50 mL	50 mL	20 mL
Programmable maximum delivery rate (continuous rate + bolus)	Yes 500 mL/hour, with high flow disposable	Yes 250 mL/hour, with standard flow disposable	Yes 175 mL/hour, with standard flow disposable
Patient-controlled access PCA (dosing)	Yes	Yes	Yes
Dose lockout time	Yes	Yes	Yes
Doses per hour limit	Yes	Yes	Yes
Delivery limit	Yes	Yes	Yes
Clinician bolus	Yes	Yes	Yes

CADD™-Solis Medication Safety Software Version 3.1, Version 2.0, and Version 1.2 Comparison Table

Characteristic	CADD™-Solis Medication Safety Software		
General Information	**Version 3.1**	**Version 2.0**	**Version 1.2**
Manufacturer	Smiths Medical ASD, Inc.	Smiths Medical ASD, Inc.	Smiths Medical ASD, Inc.
510(k) notification number and substantial equivalence determination date	K130394, pending	K111275, February 1, 2013	K072144 (Administrator), March 7, 2008 K082783 (Point of Care), December 17, 2008
Software revision level	3.1	2.0	1.2
Summary of changes/rationale for submission	Updated medication safety software applications to support intermittent bolus parameters in the CADD®-Solis Pump Version 3.0.	Updated medication safety software applications to support the five delivery modes (PCA, continuous, intermittent, step, and taper) in the CADD®-Solis VIP Pump.	Initial release.
Indications for use	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 VIP Ambulatory Infusion Pump, 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	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 VIP Ambulatory Infusion Pump, 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	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).

Characteristic	CADD™-Solis Medication Safety Software		
General Information	**Version 3.1**	**Version 2.0**	**Version 1.2**
	Infusion Pump (software revision H or higher).	Pump (software revision H or higher).	
Pump compatibility	CADD®-Solis VIP Ambulatory Infusion Pump, CADD®-Solis Ambulatory Infusion Pump and CADD-Prizm® PCS II 6101 (rev H and higher)	CADD®-Solis VIP Ambulatory Infusion Pump, CADD®-Solis Ambulatory Infusion Pump and CADD-Prizm® PCS II 6101 (rev H and higher)	CADD®-Solis Ambulatory Infusion Pump model 2100 and 2110, and CADD-Prizm® PCS II 6101 (rev H and higher)
Accessory compatibility	P/N 21-6144, Interface cable/null modem cable for CADD-Prizm® pump USB cable for the CADD®-Solis VIP pump, and CADD®-Solis pump	P/N 21-6144, Interface cable/null modem cable for CADD-Prizm® pump USB cable for the CADD®-Solis VIP pump, and CADD®-Solis pump	P/N 21-6144, Interface cable/null modem cable for CADD-Prizm® pump USB cable for the CADD®-Solis pump
PC software compatibility	Windows 2000, XP, VISTA, Windows 7 Administrator only: Windows Server 2003, Server 2008, Server 2008R	Windows 2000, XP, VISTA	Windows 2000, XP Windows Server 2003
Computer equipment	RS-232 serial port, USB, and CD-ROM	RS232 serial port, USB, and CD-ROM	RS232 serial port, USB, and CD-ROM
System Features			
Protocol Programming	Yes	Yes	Yes
View Reports	Yes	Yes	Yes
Print Reports	Yes	Yes	Yes
Save Reports	Yes	Yes	Yes
Event Log Viewing	Yes	Yes	Yes
Rx (pump) History/Settings Viewing	Yes	Yes	Yes
CQI data Collection and Retrieval	Yes	Yes	Yes
Wt based programming (PCA mode)	Yes	Yes	Yes
BarCode Printing	Yes	Yes	Yes
Password Protected	Yes	Yes	Yes
Second Nurse Verification	Yes	Yes	Yes
Drug ID verification	Yes	Yes	Yes

Characteristic	CADD™-Solis Medication Safety Software		
General Information	**Version 3.1**	**Version 2.0**	**Version 1.2**
Programming Features			
Units Programming	Yes	Yes	Yes
Concentration Programming	Yes	Yes	Yes
Continuous Rate Programming	Yes	Yes	Yes
Demand Dose Programming	Yes	Yes	Yes
Demand Dose Lockout Programming	Yes	Yes	Yes
Max Patient Weight (ranges)	Yes	Yes	Yes
Epidural Mode on/off	Yes	Yes	Yes
New Patient Feature	Yes	Yes	Yes
Program Limits (Soft and Hard Limits) programming	Yes	Yes	Yes
Bio Med Infusion Pump Programming	Yes	Yes	Yes
Pump/Module ID Storage and Retrieval	Yes	Yes	Yes
Date/Time Format	Yes	Yes	Yes
Report/Alarm/Messages/Features			
Pump Setting Reports	Yes	Yes	Yes
Continuous Quality Indicator Reports	Yes	Yes	Yes
Soft Limits Exceeded	Yes	Yes	Yes
Hard Limits Exceeded	Yes	Yes	Yes
Selective Alarms/Messages User Customizable	Yes	Yes	Yes
Drug bar code scan incorrect	Yes	Yes	Yes
Pump/Module Power Status	Yes	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 9, 2013

Smiths Medical ASD, Incorporated
Ms. Julie Tapper
Sr. Regulatory Affairs Specialist
1265 Grey Fox Road
St. Paul, MN 55112

Re: K130394
Trade/Device Name: CADD® - Solis Ambulatory Infusion Pump, Model 3.0
CADD® - Solis Medication Safety Software, Version 3.1
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEA, MRZ
Dated: November 4, 2013
Received: November 5, 2013

Dear Ms. Tapper:

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 contact 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. 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,

Kwame O. Ulmer for
-S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K130394

Device Name
The CADD®-Solis Ambulatory Infusion Pump, Model2110, Version 3.0

Indications for Use *(Describe)*
The CADD® -Solis Ambulatory Infusion Pump, Model 2110, Version 3 .0, 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, and/or an intermittent bolus, and/or with patient-controlled demand doses.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Kathleen E. Fitzgerald

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K130394

Device Name
The CADD®-Solis Medication Safety Software, Version 3.1

Indications for Use *(Describe)*
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 VIP Ambulatory Infusion Pump, CADD®-Solis Ambulatory Infusion Pump, or CADD-Prizm® PCS II Ambulatory Infusion Pump (software revision H or higher).

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).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Kathleen E. Fitzgerald

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