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August 24, 2017

Smiths Medical ADS, Inc.
Breanna Fautsch
Regulatory Affairs Specialist
6000 Nathan Lane North
Minneapolis, Minnesota 55442

Re: K170982

Trade/Device Name: CADD®- Solis Ambulatory Infusion Pump with Wireless Communication; CADD®-Solis Infusion Pump, Model 2110; PharmGuard® Administrator Medication Safety Software; CADD® Administration Sets; Wireless Communication Module (CM)

Regulation Number: 21 CFR 880.5725

Regulation Name: Infusion Pump

Regulatory Class: Class II

Product Code: MEA, MRZ, FPA, PYR

Dated: July 24, 2017

Received: July 20, 2017

Dear Ms. Fautsch:

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 Industry and Consumer Education (DICE) 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" (21 CFR 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 Industry and Consumer Education (DICE) 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,

Tara A. Ryan -S

for
Lori Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K170982

Device Name

CADD®- Solis Ambulatory Infusion Pump with Wireless Communication; CADD®-Solis Infusion Pump, Model 2110;
PharmGuard® Administrator Medication Safety Software; CADD® Administration Sets; Wireless Communication Module (CM)

Indications for Use (Describe)

CADD®- Solis Ambulatory Infusion Pump with Wireless Communication

CADD®-Solis Infusion Pump, Model 2110

The CADD®-Solis 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. 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.

PharmGuard® Administrator Medication Safety Software

The PharmGuard® Administrator Medication Safety Software allows the use of a computer to create therapy-based protocol libraries to be used with the CADD®-Solis Infusion Pump.

CADD® Administration Set

The CADD® Administration Set is designed for use with the CADD® Infusion pumps (except CADD®-Micro) to allow medication delivery from a flexible container.

Wireless Communication Module (CM)

The Wireless Communication Module is intended to be used as an accessory to provide wireless capability and battery power to a CADD®-Solis Infusion Pump, Model 2110

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K170982 510(K) SUMMARY

Manufacturer's Name: Smiths Medical

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Preparation Date: August 25, 2017

Trade Name: CADD®- Solis Ambulatory Infusion Pump with Wireless Communication
CADD®-Solis Infusion Pump, Model 2110
PharmGuard® Administrator Medication Safety Software
CADD® Administration Sets
Wireless Communication Module (CM)

Common or Usual Name: Infusion Pump

Regulation Name: Infusion Pump

Regulation Number: 21 CFR 880.5725

Product Code: FRN – Infusion Pump
MRZ – Infusion Pump Accessories
FPA – Set, Administration, Intravascular
PYR– Neuraxial Administration Set - Intrathecal delivery

Device Class: Class II

Primary Predicate Device: K130394

Secondary Predicate Device: K040636

Device Description

The CADD®- Solis Ambulatory Infusion Pump with Wireless Communication, which includes the CADD®-Solis Infusion Pump, Model 2110, the Wireless Communication Module (CM), and the PharmGuard® Administrator Medication Safety Software, work together to provide wireless communication between the pump and the server and are similar to currently marketed products.

The CADD®-Solis Infusion Pump, Model 2110 has a microprocessor and linear peristaltic pumping mechanism, similar in design to the Smiths Medical ASD, Inc. CADD®-Solis Ambulatory Infusion Pump, Version 3.0 (K130394). The user activates CADD®-Solis Infusion Pump, Model 2110 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® Administration Set is designed for use with the CADD® Infusion pumps (except CADD®-Micro) to allow medication delivery from a flexible container. The Flow Stop feature is a set-based free flow protection component (i.e. Flow Stop) that is designed to occlude the tube if the set is accidentally placed onto the pump incorrectly or becomes detached from the pump. The Flow Stop is located on the set housing, which is attached to the pump.

Intended Use

The CADD®- Solis Ambulatory Infusion Pump with Wireless Communication is intended to be used for patient care for adult and pediatric patients in multiple clinical care areas, including but not limited to post-operative, trauma, critical care, oncology, and labor and delivery. 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.

Indications for Use Statement

CADD®- Solis Ambulatory Infusion Pump with Wireless Communication

CADD®-Solis Infusion Pump, Model 2110

The CADD®-Solis 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. 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.

PharmGuard® Administrator Medication Safety Software

The PharmGuard® Administrator Medication Safety Software allows the use of a computer to create therapy-based protocol libraries to be used with the CADD®-Solis Infusion Pump.

CADD® Administration Set

The CADD® Administration Set is designed for use with the CADD® Infusion pumps (except CADD®-Micro) to allow medication delivery from a flexible container.

Wireless Communication Module (CM)

The Wireless Communication Module is intended to be used as an accessory to provide wireless capability and battery power to a CADD®-Solis Infusion Pump, Model 2110

Substantial Equivalence Discussion

The CADD®- Solis Ambulatory Infusion Pump with Wireless Communication (pump and accessories) covered by this submission is the result of modifications to the FDA cleared CADD-Solis Ambulatory Infusion Pumps, Model 2110 Version 3.0 (K130394), CADD-Solis Medication Safety Software Version 3.1 (K130394) and CADD® Administration Set with Flow Stop, Medication Cassette Reservoir with Flow Stop (K040636).

The modifications include user interface updates to a software version 4.1 and the capability of the pump to support a new optional accessory device, the Wireless Communication Module (CM). The CM connects through the battery compartment on the CADD®-Solis Infusion Pump, Model 2110 in order to wirelessly connect the pump to the Smiths Medical PharmGuard® Server. The administration sets subject devices are the same as the predicate devices with the exception of the indication which now includes intrathecal use when utilized with the CADD®-Solis Infusion Pump, Model 2110.

Comparison of Indications for Use Statements

The tables below identifies and provides comparative assessments of the indications for use between the CADD®-Solis Infusion Pump, Model 2110, PharmGuard® Administrator Medication Safety Software, and CADD® Administration Sets subject device and predicate as required per 21 CFR 807.92.

Indications for Use – Infusion Pump	
Subject Device (K170982)	Predicate Device (K130394)
CADD®-Solis Infusion Pump, Model 2110	The CADD®-Solis Ambulatory Infusion Pump,

	Model2110, Version 3.0
CADD®-Solis Infusion Pump, Model 2110 The CADD®-Solis Version 4.1 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. 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 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.

Discussion of Differences

The indications for use statements are identical.

Indications for Use – Medication Safety Software	
Subject Device (K170982) PharmGuard® Administrator Medication Safety Software	Predicate Device (K130394) The CADD®-Solis Medication Safety Software, Version 3.1
The PharmGuard® Administrator Medication Safety Software allows the use of a computer to create therapy-based protocol libraries to be used with the CADD®-Solis Infusion Pump.	<p>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).</p> <p>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).</p>

Discussion of Differences

The predicate device provides two statements, one for administrative users and one for point of care users to reflect the two separate software products. However, the subject device provides one software product and multiple user profiles within the software product. Therefore, a single indications statement is appropriate. There are no differences in the core language of the indications for use statements.

Indications for Use – Administration Sets	
Subject Device (K170982) CADD® Administration Set	Predicate Device (K040636) CADD® Medication Cassette Reservoir with Flow Stop CADD® Administration Set with Flow Stop
The CADD® Administration Set is designed for use with the CADD® Infusion pumps (except CADD®-Micro) to allow medication delivery from a flexible container.	<p>"The CADD® Medication Cassette Reservoir with Flow Stop is designed for use with the CADD® pumps (except CADD-Micro® and CADD-TPN®) for delivery of medications and fluids."</p> <p>"The CADD® Administration Set with Flow Stop is</p>

designed for use with the CADD® pumps (except CADD-Microo and CADD-TPN) for delivery of medications and fluids."

Discussion of Differences

Both statements imply medication delivery and therefore are identical in purpose.

Comparison of Device Characteristics

The tables below identifies and provides comparative assessments of significant physical and performance characteristics between the CADD Solis Infusion Pump, Medication Safety Software, and Administration Sets subject device and predicate as required per 21 CFR 807.92.

Infusion Pump

Attribute	Subject Device (K170982) CADD®-Solis Infusion Pump, Model 2110	Predicate Device (K130394) The CADD®-Solis Ambulatory Infusion Pump, Model2110, Version 3.0	Comparison
Manufacturer	Smiths Medical ASD – Pump Plexus Corp. - CM	Smiths Medical ASD	-
Pump Model Number	Model 2110	Model 2110	-
Pump Firmware version	Version 4.1	Version 3.0	See discussion of differences (1)
Pump type/ principle of operation	Linear peristaltic	Linear peristaltic	Identical
Materials of construction	Same for subject and predicate CADD®-Solis Pumps	Same for subject and predicate CADD®-Solis Pumps	Identical
Display	Color display with 320 x 320 pixels	Color display with 320 x 320 pixels	Identical
Wireless capability	Yes, with installed CM	No	See discussion of differences (2)
Power requirements	Rechargeable CM AC Adapter	4 (“AA”) batteries AC adapter Rechargeable battery pack	See discussion of differences (3)
Pump packaging	Foam insert, hardboard box	Foam insert, hardboard box	Identical
CM Packaging	Foam insert, hardboard box	n/a	n/a
USB port	Yes	Yes	Identical
AC adapter	Yes	Yes	Identical
AC power cord	Yes	Yes	Identical
Remote dose cord	Yes	Yes	Identical
Pole mount adapter	Yes	Yes	Identical
Carrying pouch	Yes	Yes	Identical
Lockbox	Yes	Yes	Identical
Medication cassette reservoir	Yes	Yes	Identical
Administration set	Yes	Yes	Identical
Extension set	Yes	Yes	Identical
Intermittent	Yes	Yes	Identical

(programmed intermittent bolus)			
Continuous infusion	Yes	Yes	Identical
Continuous infusion with Bolus (PCA)	Yes	Yes	Identical
Intermittent (programmed intermittent bolus)	Yes	Yes	Identical
Continuous infusion	Yes	Yes	Identical
Maximum clinician bolus	50 mL	50 mL	Identical
Programmable maximum delivery rate (continuous rate + bolus)	Yes 500 mL/hour, with high flow disposable	Yes 500 mL/hour, with high flow disposable	Identical
Patient controlled access PCA (dosing)	Yes	Yes	Identical
Dose lockout time	Yes	Yes	Identical
Doses per hour limit	Yes	Yes	Identical
Delivery limit	Yes	Yes	Identical
Clinician bolus	Yes	Yes	Identical
Maximum clinician bolus	50 mL	50 mL	Identical
Programmable maximum delivery rate (continuous rate+bolus)	Yes 500 mL/hour, with high flow disposable	Yes 500 mL/hour, with high flow disposable	Identical
Medication Safety Software	Version 4.1	Version 3.1	Identical

Discussion of Differences

- (1) Pump Firmware Update: firmware version update to accommodate updates in software. This was verified with software testing in accordance with IEC 62304:2006 Medical device software – software life cycle process and the Agency’s Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.
- (2) Data Transmission: update in means of data transmission from physical connection of USB to wireless connection using the CM optional accessory. Design Verification and Validation testing demonstrates the wireless data transmission as meeting the acceptance criteria and intended use as well as USB data transmission utilized in the predicate device.
- (3) Power Requirements: the CM accessory contains a rechargeable battery pack within the confines of the CM container, which provides a similar type of power source for the pump as the standalone rechargeable battery pack that is included as a cleared accessory for the predicate device. Performance of the CM accessory was verified and validated through bench testing.

Medication Safety Software

Attribute	Subject Device (K170982) PharmGuard® Medication Safety Software	Predicate Device (K130394) The CADD®-So1is Medication Safety Software, Version 3.1	Comparison
Manufacturer	Smiths Medical ASD	Smiths Medical ASD	Identical
PC software	Windows 2000, XP, VISTA,	Windows 2000, XP, VISTA,	See discussion of

compatibility	Windows 7, Windows 8 Administrator only: Windows Server 2003, Server 2008, Server 2008R	Windows 7, Administrator only: Windows Server 2003, Server 2008, Server 2008R	differences (1)
Protocol programming	Yes	Yes	Identical
Multi-line drug names	Yes	No	See discussion of differences (2)
Profiles function	Yes	No	See discussion of differences (3)
View reports	Yes	Yes	Identical
Print reports	Yes	Yes	Identical
Save reports	Yes	Yes	Identical
Event log viewing	Yes	Yes	Identical
Rx (pump History/Settings Viewing	Yes	Yes	Identical
CQI data collection and retrieval	Yes	Yes	Identical
Wt based programming (PCA mode)	Yes	Yes	Identical
BarCode printing	Yes	Yes	Identical
Password protected	Yes	Yes	Identical
Second nurse verification	Yes	Yes	Identical
Drug ID verification	Yes	Yes	Identical
Units programming	Yes	Yes	Identical
Concentration programming	Yes	Yes	Identical
Demand Dose programming	Yes	Yes	Identical
Max patient weight (ranges)	Yes	Yes	Identical
Epidural Mode on/off	Yes	Yes	Identical
New patient feature	Yes	Yes	Identical
Program limits (soft and hard limits) programming	Yes	Yes	Identical
Biomed infusion pump programming	Yes	Yes	Identical
Pump/Module ID Storage and retrieval	Yes	Yes	Identical
Date/Time format	Yes	Yes	Identical
Daylight Savings Time feature	Yes	No	See discussion of differences (4)
Asset ID Feature	Yes	No	See discussion of differences (5)

Units programming	Yes	Yes	Identical
Concentration programming	Yes	Yes	Identical
Continuous rate programming	Yes	Yes	Identical
Demand dose programming	Yes	Yes	Identical

Discussion of Differences

- (1) PC Software Capability: the subject device supports Windows 8 PC Software capability. This was verified with software testing in accordance with IEC 62304:2006 Medical device software – software life cycle process and the Agency’s Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.
- (2) Multi-line Drug Names: the subject device software updates to the pump allow for multiple lines of drug names to appear on the pump screen compared to the single line drug name capability of the predicate device pump. This change enhances ease of use as the user can see the full drug name instead of having to scroll through lines. This feature was verified with software testing in accordance with IEC 62304:2006 Medical device software – software life cycle process and the Agency’s Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. This feature was validated with Human Factors testing.
- (3) Profiles Function: the subject device software updates to the pump allow for user defined optional profiles to allow the user for easier organization of information stored on the pump. This feature was verified with software testing in accordance with IEC 62304:2006 Medical device software – software life cycle process and the Agency’s Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. This feature was validated with Human Factors testing.
- (4) Daylight Savings Time Auto Adjust Feature: the subject device can be configured to automatically update the time to account for daylight savings where the predicate device allows for manual entry of time adjustment only. This feature was verified with software testing in accordance with IEC 62304:2006 Medical device software – software life cycle process and the Agency’s Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.
- (5) Asset ID Feature: the subject device has the optional feature of allowing the customer to set up an asset pump ID for each pump as a means of additional pump identification. This feature was verified with software testing in accordance with IEC 62304:2006 Medical device software – software life cycle process and the Agency’s Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. This feature was validated with Human Factors testing.

Administration Sets

The CADD® Administration Sets do not have any feature or function changes and are similar in design, function, and intended use to the predicate CADD® Administration Sets (K040636). The CADD® Administration Sets included in this submission may now be used to delivery medication to the intrathecal space as established through pre-clinical GLP neurotoxicity studies, chemical characterization and a toxicology assessment.

Conclusion

The differences in the indications for use statements and device characteristics are supported through non-clinical performance testing and do not raise new or different questions of safety and effectiveness.

Summary of Non-Clinical Performance Testing

A safety assurance case was provided for the CADD®- Solis Ambulatory Infusion Pump with Wireless Communication, which includes the CADD®-Solis Infusion Pump, Model 2110, the Wireless Communication Module (CM), and the

PharmGuard® Administrator Medication Safety Software, as recommended in the FDA guidance document, Infusion Pumps Total Product Life Cycle.

The stated goal of the safety assurance case is:

- The CADD-Solis Ambulatory Infusion Pump System is reasonably safe for use in its intended environment by its intended users

The assurance case defined the device system, including the indications for use, system definition, operational description, patient populations, and use environments. The supporting assurance arguments covered the following attributes:

The device is properly identified and defined

- The process used to define new products and establish their requirements build a foundation for safe products
- Clinical requirements define a safe system for the intended indications for use
- Requirements are driven by applicable standards for the intended use, and markets of distribution are identified

The device design is adequately verified and validated

- The developmental processes used take the establish requirements and implement them, resulting in safe products

The device risks are acceptably mitigated

- Risk analysis process identifies and manages safety requirements by identifying all hazards to safety, causes of those hazards, controls to mitigate those hazards, and assessing the effectiveness of those controls

The device is adequately reliable to ensure its safety over its intended use life.

- The production process results in the manufacturing of products which, when used alone or in combination, form a safe system
- The post-launch processes are in place to maintain safe products once they have been shipped to the customer

The following evidence was included in the assurance case:

Performance Test Summary – System verification and validation activities for CADD®- Solis Ambulatory Infusion Pump with Wireless Communication, which includes the CADD®-Solis Infusion Pump, Model 2110, the Wireless Communication Module (CM), and the PharmGuard® Administrator Medication Safety Software, confirmed that the system modifications meets user needs and design inputs. All the testing met the acceptance criteria.

- The infusion pump basic safety and essential performance verification was completed in accordance with IEC 60601-1 General requirements for basic safety and essential performance.
- Human factors evaluations have been conducted to validate the effectiveness of use error related mitigations in accordance with the Agency’s Guidance Document, “Applying Human Factors and Usability Engineering to Medical Devices” and IEC 62366-1:2007 Application of usability engineering to medical devices
- Electrical and Electromagnetic Compatibility testing were conducted. The CADD®- Solis Ambulatory Infusion Pump with Wireless Communication, which includes the CADD®-Solis Infusion Pump, Model 2110, the Wireless Communication Module (CM), and the PharmGuard® Administrator Medication Safety Software, complies with following standards:
 - Electrical Safety per IEC 60601-1 and IEC 60601-1-12
 - EMC testing per IEC 60601-1-2
 - IEC 60601-1-6:2013 Medical electrical equipment – Part 1-6: General requirements for safety: usability
 - 2054 UL Standard for Safety Household and Commercial Batteries - Second Edition; Reprint with revisions through and including September 14, 2011

- IEC 62122 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made for them, for use in portable applications
- Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers” (catalog number 7351731)
- Software Verification and Validation per the Agency’s “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,” “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices” and IEC 62304:2006 Medical device software – software life cycle process
- Cleaning and Disinfection Validation for the CADD®- Solis Ambulatory Infusion Pump with Wireless Communication, which includes the CADD®-Solis Infusion Pump, Model 2110, the Wireless Communication Module (CM), and the PharmGuard® Administrator Medication Safety Software, confirmed that the new accessories meets the cleaning and disinfection requirements.
- GLP pre-clinical studies were completed to demonstrate each of the CADD® Administration Sets proposed for delivery of fluids to the epidural and subarachnoid spaces are free from unacceptable neurotoxicological risk.
- A Chemical Characterization, Toxicological Risk Assessment, and in vivo and in vitro Biocompatibility studies were completed in accordance with ISO 10993-1:2009/ (R) 2013 Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
- Packaging and Shipping verification was conducted in accordance with ASTM D4169 Standard Practice for Performance Testing of Shipping Containers and Systems

Conclusion

The testing conducted demonstrates that the CADD®- Solis Ambulatory Infusion Pump with Wireless Communication, which includes the CADD®-Solis Infusion Pump, Model 2110, the Wireless Communication Module (CM), and the PharmGuard® Administrator Medication Safety Software with changes described meet the design requirements of the cleared predicate devices. Therefore, the CADD®- Solis Ambulatory Infusion Pump with Wireless Communication, which includes the CADD®-Solis Infusion Pump, Model 2110, the Wireless Communication Module (CM), and the PharmGuard® Administrator Medication Safety Software that is the subject of this submission is substantially equivalent to its predicate.

Clinical Tests

Not Applicable

Conclusions

The modifications pertain to the software update, additional communication module accessory, and expansion of the administration sets to include intrathecal delivery when used with the CADD® Infusion Pump. There are no changes the basic infusion pump technology. The modifications are supported by non-clinical testing.

The evaluation of the CADD®- Solis Ambulatory Infusion Pump with Wireless Communication classification, indications for use, comparative evaluation to the predicate devices, K1310394 and K040636, and non-clinical performance testing demonstrate that the device is substantially equivalent to the legally marketed predicate device in as required per 21 CFR 807.92(3). Device testing met pre-defined acceptance criteria and did not raise new or different question of safety or effectiveness.