March 26, 2021

Chengdu Shifeng Medical Technology Co., Ltd.
% Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
44 Oak Street
Stoneham, Massachusetts 02180

Re: K201634
Trade/Device Name: RG 3ml Medication Cartridge
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: MRZ
Dated: February 23, 2021
Received: February 23, 2021

Dear Maureen O'Connell:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For CAPT Alan Stevens
Acting Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201634

Device Name
RG 3ml Medication Cartridge

Indications for Use *(Describe)*
The RG 3ml Medication Cartridge is designed for use in hospitals and outpatient care environments with the CADD-MS3 Ambulatory Infusion Pump for subcutaneous infusion of medication in adults.

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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K201634 510(k) SUMMARY

Chengdu Shifeng Medical Technology Co., Ltd.
RG 3ml Medication Cartridge

510(k) Owner
Chengdu Shifeng Medical Technology Co., Ltd.
No 31, Yinyuan Road
Jinhua Town
Xinjin County
Chengdu, Sichuan, China

Submission Correspondent
Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
44 Oak Street
Stoneham, MA 02180
Phone: 978-207-1245

Date Prepared: March 26, 2021

Subject Device

Trade Name:	RG 3ml Medication Cartridge
Common or Usual Name:	Infusion Pump Syringe
Classification Name:	Pump, Infusion
Device Classification:	21 CFR 880.5725
Class	II
Product Code:	MRZ
Classification Panel:	General Hospital

Predicate Device

Trade Name:	Smiths Medical MD, Inc. CADD-MS®3 Ambulatory Infusion Pump
510(k) Reference:	K051568
Common or Usual Name:	Infusion Pump Syringe
Classification Name:	Pump, Infusion
Device Classification:	21 CFR 880.5725
Class	II
Product Code:	FRN
Classification Panel:	General Hospital

Device Description
The RG 3ml Medication Cartridge is a sterile, single-use, non-pyrogenic, 3.0 ml piston syringe intended for use with the Smiths Medical MD, Inc. CADD-MS®3 Ambulatory Infusion Pump. The CADD-MS®3 Ambulatory Infusion Pump requires use of a 3 ml medication cartridge and an infusion set. The RG 3ml Medication Cartridge consists of a hollow barrel, movable plunger with

O-rings for sealing and a male Luer lock fitting at the distal end. The male Luer lock fitting of the cartridge is connected to the female Luer fitting of an infusion set. The reservoir is placed in the CADD-MS®3 Ambulatory Infusion Pump to achieve its intended use. The RG 3ml Medication Cartridge is available with a 0.7mm (22G) x 12.5mm (1/2in.) needle and cap. The needle is attached to the end of the RG 3ml Medication Cartridge and operates as a syringe to withdraw medication from a vial.

After the medication is filled in the RG 3ml Medication Cartridge, the plunger stopper is removed to allow the RG 3ml Medication Cartridge to fit inside the Smiths CADD-MS®3 Infusion Pump. A cartridge cap from the Smiths CADD-MS®3 Infusion Pump secures the RG 3ml Medication Cartridge into place. An infusion set is then attached to the luer lock fitting of the RG 3ml Medication Cartridge.

Indications for Use

The RG 3ml Medication Cartridge is designed for use in hospitals and outpatient care environments with the CADD-MS®3 Ambulatory Infusion Pump for subcutaneous infusion of medication in adults.

Comparison of Technological Characteristics with the Predicate Device

Table 1 provides a tabular presentation of the RG 3ml Medication Cartridge compared with the predicate device. Both the subject device and the 3 ml cartridge component of the predicate device are intended for use in delivering medication utilizing the CADD-MS®3 Ambulatory Infusion Pump. The table below also assess the differences to demonstrate that there no new or different questions of safety and effectiveness between the subject and predicate device.

Table 1
RG 3ml Medication Cartridge Substantial Equivalence

Characteristic	**RG 3ml Medication Cartridge**	**Smiths Medical MD, Inc. CADD-MS®3 Ambulatory Infusion Pump, 3 mL Cartridge Reservoir**	**Discussion of Differences**
510(k) Number	K201634	K051568	N/A
Product Code	MRZ	FRN	Both are within Infusion pump regulation : 21 CFR 880.5725, which supports substantial equivalence
Indications for Use	The RG 3ml Medication Cartridge is designed for use in hospitals and outpatient care environments with the CADD-MS®3 Ambulatory Infusion Pump for subcutaneous	The Smiths Medical Inc. 3 ml Cartridge Reservoir Indications for use are: The Smiths Medical MD, Inc. 3-ml Cartridge Reservoir is designed for use with	The predicate device includes both a pump and cartridge. The subject device indications are compared to the cartridge indications for use and support

	infusion of medication in adults.	the CADD-MS 3 for delivering medication.	substantial equivalence
Use Type	Prescription Use	Prescription Use	Same
Cartridge Use	With CADD-MS®3 Ambulatory Infusion Pump	With CADD-MS 3 Ambulatory Infusion Pump	Same
Volume	3 ml	3 ml	Same
Sterility Status	Sterile, single use	Sterile, single use	Same
Biocompatibility	Yes per ISO 10993-1	Yes per ISO 10993-1	Same

Non-Clinical Performance Testing
The following non-clinical/performance testing was used to support substantial equivalence:

The materials used for the RG 3ml Medication Cartridge comply with biocompatibility requirements outlined in ISO 10993-1:2009 and the Guidance for Industry and Food and Drug Administration Staff, *Use of International Standard ISO 10993 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process* and are considered to be biocompatible.

The following biocompatibility testing was performed:

Test	Standard
Cytotoxicity	ISO 10993-5:2009
Dermal Sensitization	ISO 10993-10:2010
Intracutaneous Irritation Test	ISO 10993-10 :2010
Acute Systemic Toxicity	ISO 10993-11 :2017
Subacute Toxicity	ISO 10993-11 :2017
Pyrogenicity	ISO 10993-11 :2017
Hemolysis (Direct Contact and Indirect Contact)	ISO 10993-4 :2017

The device has a 2-year shelf life. This was supported by sterility, packaging, and performance testing.

Ethylene Oxide is used to sterilize the device and validation was provided per FDA recognized standard ISO 11135: 2014 - Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices. A sterility assurance level (SAL) was validated to 10^{-6}.

Packaging testing was also conducted via the following FDA recognized standards: ASTM F2096 (Bubble Test), ASTM F1929 (Dye Penetration Test), ASTM F1886 (Visual Inspection), STM D4169 (Simulated Shipping), and ISO 11607-2 (General Packaging Standard). In addition, seal strength testing was conducted on the packaging.

The following performance testing was conducted using Smiths Medical MD, Inc. CADD-MS®3 Ambulatory Infusion Pump:

- ISO 7886-2:2020 (Flow rate testing using the Smiths Medical MD, Inc. CADD-MS®3 Ambulatory Infusion Pump)
- Occlusion Alarm Testing
- Cartridge Loading and Detection Testing
- Cartridge Volume Alarm Testing

In order to establish compatibility with the CADD-MS 3 Ambulatory Infusion Pump and demonstrate adequate performance within the pump specifications as compared to the Smiths Medical CADD-MS 3 Cartridge Reservoir, flow rate accuracy testing was conducted using the RG 3 mL Medication Cartridge and the CADD-MS 3 Ambulatory Infusion Pump. Results showed that the RG 3ml Medication Cartridge when used with the CADD-MS®3 Ambulatory Infusion Pump passed all testing required in ISO 7886-2 and flow rate testing within pump specifications, supporting substantial equivalence to the predicate device.

Conclusion

Differences between the intended use and technological characteristics of the subject device compared to the predicate do not raise different questions of safety and effectiveness. The performance of the device is supported by non-clinical testing and risk management activities. The RG 3ml Medication Cartridge is Substantially Equivalent (SE) to the Smiths Medical MD, Inc. CADD-MS®3 Ambulatory Infusion Pump, 3 mL Cartridge Reservoir, cleared under K051568.