June 15, 2023

Gilero, LLC
Jessica Czamanski
Regulatory Consultant
635 Davis Drive Ste 100
Morrisville, North Carolina 27560

Re: K230718
Trade/Device Name: UTC 3mL Medication Cartridge
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: MRZ
Dated: March 14, 2023
Received: March 15, 2023

Dear Jessica Czamanski:

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); 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,

Jake K. Lindstrom -S

Digitally signed by Jake K. Lindstrom -S
Date: 2023.06.15 14:35:28 -04'00'

Jake Lindstrom, Ph.D.
Assistant 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)*
K230718

Device Name
UTC 3mL Medication Cartridge

Indications for Use *(Describe)*
The UTC 3 ml Medication Cartridge is intended for use in hospital and outpatient care environments with the CADD-MS® 3 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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K230718- 510(k) SUMMARY

I. Submitter

Submitter's Name: Gilero LLC

Contact Person: James Fentress
Director, Research, Development, and Regulatory Policy

Address: 635 Davis Dr.
Ste 100
Morrisville, NC 27560 USA

Telephone: +35 387-943-5990

Email: jfentress@gilero.com

Date Preparation: June 15, 2023

II. Application Correspondent

Contact's Name: Gilero, LLC

Contact Person: Jessica Czamanski
Regulatory Consultant

Address: 635 Davis Dr.
Ste 100
Morrisville, NC 27560

Telephone: (754) 422-9101

Email: jczamanski@gilero.com

III. Subject Device

Trade Name: UTC 3mL Medication Cartridge

Common Name: Infusion Pump Syringe

Classification Name: Accessories, Pump, Infusion

Product Classification: Class II

Regulation Number: 21 CFR §880.5725

Product Code: MRZ

IV. Predicate Device

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

510(k) Number: K051568

V. Device Description

The UTC 3 mL Cartridge (UTC Cartridge) is a is a sterile, single-use cartridge intended for use with the Smiths Medical MD, Inc. CADD-MS®3 Ambulatory Infusion Pump. The UTC Cartridge is for use in hospitals and outpatient care environments.

The UTC 3 mL Medication Cartridge consists of 3 primary components: a 3mL cartridge that looks like a small syringe, 22G x 0.5 in. needle, and protective cap.

The distal end of the device has a male luer lock used to attach the needle and withdraw medication from a vial. Once filled, the plunger is removed, needle is discarded, and protective cap is place on the luer until the cartridge is inserted into the CADD-MS 3 Infusion Pump and secured into place with the infusion pump's lid. The protective cap can then be discarded and the male luer can then be attached to the female luer of an infusion set.

VI. Indications for Use

The UTC 3 mL Medication Cartridge is intended for use in hospital and outpatient care environments with the CADD-MS 3 Ambulatory Infusion Pump for subcutaneous infusion of medication in adults.

VII. Comparison of Technological Characteristics with the Predicate Devices

The subject and predicate devices have the same intended use. Both are cartridges comprised of the same components, designed to be used with the CADD-MS™ 3 Infusion Pump. The predicate device's barrel, plunger, and plunger rod are made from a polypropylene resin that has been discontinued. The subject device components will also be made from polypropylene, supplied by a different supplier. Furthermore, the

indication for use of the predicate device lacks specificity around patient population and environment of use. The subject device's indications include environment of use, patient population, and limit the use of the device to subcutaneous infusion only. **Table 5-1** provides a comparison of the subject and predicate devices.

Table 5-1: General Technological Characteristics Comparison

Product Features	Subject United Therapeutics Corporation's UTC 3mL Medication Cartridge	Predicate Smiths Medical MD, Inc.'s Smiths Medical MD, Inc 3ml cartridge reservoir (K051568)	Substantial Equivalence Determination
Classification	Class II	Class II	-same-
Product Code	MRZ	FRN	Different The predicate was cleared within the pump submission, hence the different product code. A recently cleared cartridge, cleared independent from the pump, has been cleared under product code MRZ.
Regulation Number	21 CFR §880.5725	21 CFR §880.5725	-same--
Device Classification Name	Infusion Pump	Infusion Pump	-same-
Indications for Use	The UTC 3 mL Medication Cartridge is intended for use in professional healthcare and outpatient settings with the CADD-MS 3 Ambulatory Infusion Pump for subcutaneous infusion of medication in adults.	The Smiths Medical MD, Inc. 3-ml Cartridge Reservoir is designed for use with the CADD-MS™ 3 for delivering medication.	Different The subject device's indications for use, limit use to adult patients, specify environment of use, and limit use to subcutaneous infusion only. These differences limit the use and thus, do not raise new questions for safety or effectiveness. Therefore, the subject device is

Table 5-1: General Technological Characteristics Comparison

Product Features	Subject United Therapeutics Corporation's UTC 3mL Medication Cartridge	Predicate Smiths Medical MD, Inc.'s Smiths Medical MD, Inc 3ml cartridge reservoir (K051568)	Substantial Equivalence Determination
			substantially equivalent to its predicate.
Materials	Polypropylene	Polypropylene	-same
Environment of Use	Hospital and Outpatient	Hospital and Outpatient	-same-
Mechanism of Action	The cartridge is used by first filling it with medication and then inserting the pre-filled cartridge to the CADD-MS 3 Infusion Pump. The user will attach the needle to the luer of the device, extract medication from a vile, remove the needle and plunger, insert into the Infusion Pump and then attach to the female luer of an administration set for subcutaneous infusion.	The cartridge is used by first filling it with medication and then inserting the pre-filled cartridge to the CADD-MS 3 Infusion Pump. The user will attach the needle to the luer of the device, extract medication from a vile, remove the needle and plunger, insert into the Infusion Pump and then attach to the female luer of an administration set for subcutaneous infusion.	-same-
Pump Compatibility	With CADD-MS® 3 Ambulatory Infusion Pump	With CADD-MS® 3 Ambulatory Infusion Pump	-same-
Sterility Status	Sterile, via ethylene oxide	Sterile, via ethylene oxide	-same-
Volume	3mL	3mL	-same-
Biocompatibility	per ISO 10993-1	per ISO 10993-1	-same-
Use Type	Prescription Use	Prescription Use	-same-
Barrel Dimensions	1.898 x 0.550" (L x OD)	1.898 x 0.550" (L x OD)	-same-
Thumb Rest Dimensions	0.525 x 0.525" Square	0.525 x 0.525" Square	-same-

Table 5-1: General Technological Characteristics Comparison

Product Features	Subject United Therapeutics Corporation's UTC 3mL Medication Cartridge	Predicate Smiths Medical MD, Inc.'s Smiths Medical MD, Inc 3ml cartridge reservoir (K051568)	Substantial Equivalence Determination
Graduations	0.2mL increments with differentiating graduations at 1, 2, and 3 mL	0.2mL increments with differentiating graduations at 1, 2, and 3 mL	-same-

VIII. Performance Data

The following performance data was considered in support of the substantial equivalence determination.

The following tests were performed to demonstrate that the proposed UTC Cartridge met the applicable design and performance requirements and support a determination of substantial equivalence. Where applicable, testing was done per applicable ISO and other international standards.

a. Performance Testing

The sterile, single use UTC 3ml Medication Cartridge described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standards:

- ISO 7886-1:2017 Sterile hypodermic syringes for single-use – Part 1: Syringes for manual use
- ISO 7886-2:2020-04 Sterile hypodermic syringes for single-use – Part 2: Syringes for use with power-driven syringe pumps
- ISO 594-1:1986 Conical fitting with 6% (Luer) taper for syringed, needles and certain other medical equipment – Part 1: General requirements
- ISO 594-2:1998 Conical fitting

b. Biocompatibility

Biocompatibility testing was conducted in accordance with the FDA Guidance Document "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process," September 4, 2020, as recognized by FDA.

The proposed UTC Cartridge is considered an externally communicating, prolonged exposure device that indirectly contacts the blood path. Therefore, the following tests were completed:

- Cytotoxicity
- Irritation
- Sensitization
- Acute Systemic Toxicity
- Pyrogenicity
- SubacuteToxicity
- Hemocompatibility

Particulate testing was conducted in accordance with USP<788>Particulate Matter in Injection and met the USP acceptance criteria.

c. Sterilization

The UTC 3mL Medication Cartridge is sterilized with Ethylene Oxide using ISO 113135:2014, validation method by Overkill Approach (e.g., Half-Cycle method) and pyrogen test method using Bacterial Endotoxin testing.

- Packaging integrity testing after environment conditioning and simulated transportation in accordance with ASTM D4169-16, was conducted on the final, packaged, and sterile devices. All packaging deemed acceptable for protection of product and sterility maintenance.

- Sterile Barrier Packaging Testing performed on the proposed device:

    - Dye Penetration Test - ASTM 1929
    - Visual Inspection Test - ASTM F1886/F1886M-16
    - Bubble Leak Test - ASTM F2069-11

- Shelf-Life of 1 year is validated using FDA recognized standard ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

IX. Conclusion

The proposed UTC 3mL Medication Cartridge has the same intended use, mechanism of operation and fundamental technology, and similar materials compared to the predicate device, Smiths Medical MD, Inc. 3 ml Cartridge Reservoir (K051568). Any differences in the materials do not raise any new questions or concerns of safety and effectiveness. The information provided in this submission demonstrates that the subject device is substantially equivalent to its predicate.