May 6, 2021

Gilero, LLC
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K201936
Trade/Device Name: SmartSite Bag 500mL, SmartSite Bag 250 mL, SmartSite Bag 100 mL
Regulation Number: 21 CFR 880.5025
Regulation Name: I.V. container
Regulatory Class: Class II
Product Code: KPE
Dated: March 29, 2021
Received: March 30, 2021

Dear Prithul Bom:

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,

CAPT Alan Stevens
Director (acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201936

Device Name
SmartSite™ Bag

Indications for Use *(Describe)*
The SmartSite™ Bag is an empty container used for administration of intravenous solutions to the patient using an intravascular administration set. Medication transfer in and out of the container is done using aseptic technique.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Company Name: Gilero, LLC
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Company Phone: +1 (919) 595-8220

Official Contact: Kristin Benokraitis
Phone: +1 (919) 595-8223
E-mail: kristinb@gilero.com

Submission Date: May 5, 2021

Device Identification:

Trade Name:	SmartSite™ Bag
Common Name:	Container, I.V.
Device Class:	II
Regulation Number:	21 CFR 880.5025
Regulation Name:	I.V. Container
Product Code:	KPE
Review Panel:	General Hospital

Predicate Device:

Manufacturer:	Valmed s.r.l
Trade Name:	Empty EVA Bag
510(k):	K181393

Device Description:
The SmartSite™ Bag is a single-use, empty IV container, which will be available in 100mL, 250mL, and 500mL product sizes. The SmartSite™ Bag is labeled as sterile fluid path, and contains both an add port and a spike port. The add port facilitates aseptic transfer of medication(s) into or out of the bag. The spike port contains a twist-off protective seal. Either the add port or the spike port can be connected to an intravenous (IV) administration set for medication delivery to the patient. The add port may be repeatedly accessed in accordance with the Directions for Use (DFU). The SmartSite™ Bag may be used for up to 24 hours after the initial access of the add port, consistent with prescribing information for the medications used.

Indications for Use:
The SmartSite™ Bag is an empty container used for administration of intravenous solutions to the patient using an intravascular administration set. Medication transfer in and out of the container is done using aseptic technique.

Technological Characteristics and Substantial Equivalence:
The following chart presents an overview of comparisons between the subject device (SmartSite™ Bag), and the predicate device (Valmed s.r.l Empty EVA Bag):

Device Attribute	SUBJECT: [Gilero] SmartSite™ Bag	PREDICATE: [Valmed] Empty EVA Bag	Assessment of Equivalence
Device Class	II	II	Equivalent
Device Classification Name	I.V. Container	I.V. Container	Equivalent
Regulation Number	21 CFR 880.5025	21 CFR 880.5025	Equivalent
Product Code	KPE	KPE	Equivalent
Indications for use	The SmartSite™ Bag is an empty container used for administration of intravenous solutions to the patient using an intravascular administration set. Medication transfer in and out of the container is done using aseptic technique.	The Empty EVA Bag is an empty container used for administration of intravenous solutions to the patient using an intravascular administration set. Medication transfer in and out of the container is done using aseptic technique.	Equivalent The indications for use of the Subject SmartSite™ Bag and predicate device are identical
Intended use	The SmartSite™ Bag is an empty container used for administration of intravenous solutions to the patient using an intravascular administration set. Medication transfer in and out of the container is done using aseptic technique.	The Empty EVA Bag is an empty container used for administration of intravenous solutions to the patient using an intravascular administration set. Medication transfer in and out of the container is done using aseptic technique.	Equivalent The intended use for the Subject SmartSite™ Bag is identical to the predicate and is also the same as the indications for use.
Intended Users	Pharmacists, pharmacy technicians, hospital staff nurses, and homecare nurses	Adequately trained staff	Equivalent. Both the subject device and the predicate device are intended to be used by personnel appropriately trained and authorized to use bags for medication preparation and delivery.
Principles of Operation	Empty bags are filled by connecting to containers containing one or more solutions through the add port. The self-closing add port does not require clamping to secure the contents. Contents are secured through the passive action of the add port. IV sets can be attached to the spike port, or the add port to	Empty bags are filled by connecting to containers containing one or more solutions through standard spikes and tubing. After filling, the bags are clamped to secure the contents prior to administration. IV sets are attached through the spike port and twist-off	Equivalent. Both the subject device and predicate device are filled by the user through an add port. The subject device contains a single add port; whereas the predicate device contains two add ports. Both the subject device and predicate device

Device Attribute	SUBJECT: [Gilero] SmartSite™ Bag	PREDICATE: [Valmed] Empty EVA Bag	Assessment of Equivalence
	facilitate delivery of the medication to the patient.	connector.	contain a spike port to connect an IV administration set for delivery of the medication to the patient. The subject device also allows the user to connect the IV administration set to the add port. These differences present no new questions of safety or effectiveness when compared to the predicate, since both the subject and predicate devices provide a mechanism for safe filling of the bag and administration of the medication to the patient using an IV administration set.
Technology and Design	The device includes a spike port and the add port. The add port allows for medication(s) to be added to the bag. An IV administration set can be connected to the bag to dispense medication.	The EVA bags include an outflow tube and a connector to the transfer set. Additional medications can be added to the container using the medication port. A capsule closes the medication port after use. The bags are clamped after filling by the means of inviolable clamps. An IV set is connected to the bag to dispense medications.	Equivalent. Both the subject and predicate device include design features to allow the user to fill the bag and attach an IV administration set for delivery of the medication.
Biocompatibility	Acceptable biological risk established by demonstrating that the device meets ISO 10993. See Section 15 – Biocompatibility.	Acceptable biological risk established by demonstrating that the device meets ISO 10993	Equivalent.
Sterilization	SAL of 10^{-6}	SAL of 10^{-6}	Equivalent.
Reuse	Single-use only	Single-use only	Equivalent

Substantial Equivalence Discussion:
The SmartSite™ Bag is substantially equivalent to the predicate Valmed s.r.l. Empty EVA Bag. The subject device and the predicate device have identical indications for use, and a similar intended use. Both devices are labeled as sterile fluid path, and are single-use devices. Any difference in materials between the two products has been evaluated through ISO 10993 testing, which demonstrates material safety.

Both the subject and predicate devices include add ports, which allow the user to fill the bag. Similarly, both the subject device and predicate device include a means for attaching an IV administration set for delivering medication to the patient. The two primary technological differences between the subject and predicate devices are the number of add ports and their function. The predicate device contains two add ports. The first add port is for initial bulk fill of the bag. Since this port is designed only to be used once, it is not disinfectable, and is sealed using an inviolable clamp. The second add port is used for additional fill or additions (e.g. a drug is added to the initial fill of saline diluent).

The subject device has only a single add port. Since this port is disinfectable, however, it can be safely used multiple times. The empty SmartSite™ Bag can be filled with diluent using the add port, disinfected, and then the same port used to add a drug for dilution.

The second technological difference also arises from the add port. Since the subject device add port is disinfectable, and is co-located with the spike port relative to the filled drug in the bag, it can be used to administer the drug using an IV set equipped with a ISO 594 compatible male Luer.

Although the SmartSite™ Bag contains minor differences in design when compared to the predicate device these differences do not change the intended use and do not raise new questions of safety and effectiveness.

Discussion of Non-clinical Tests:
The following non-clinical tests were conducted to demonstrate substantial equivalence to the predicate device.

Biocompatibility:
The SmartSite™ Bag, like the predicate device, was evaluated for biocompatibility appropriate to the contact characterization (type and duration), in accordance with the requirements of ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, and the FDA Guidance for Industry - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". Specific testing included:

- Extractable and Leachables testing and toxicological risk evaluation
- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Acute Systemic Toxicity
- Subacute/Subchronic Toxicity
- Material-Mediated Pyrogenicity

- Hemocompatibility

Bacterial Endotoxin:
Bacterial Endotoxin testing was conducted to demonstrate the product meets endotoxin requirements of <0.5EU/mL.

Sterilization Validation:
The SmartSite™ Bag is sterilized using irradiation in accordance with a validated sterilization cycle. The following standards were referenced during the sterilization validation process:

- ANSI/AAMI/ISO 11137-1:2006/(R) 2015&A1 2013 Sterilization of Health Care Products-Radiation-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ANSI/AAMI/ISO 11137-2:2013/(R) 2019 Sterilization of Health Care Products-Radiation-Part 2: Establishing the sterilization dose
- ANSI/AAMI/ISO TIR 13004:2013 Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VDmaxSD

Performance Testing:
The SmartSite™ Bag is tested to verify compliance with relevant sections of:

- ISO 15747 (2018) Plastic containers for intravenous injections

Particulate Testing:
The SmartSite™ Bag was tested to demonstrate the product meets particulate requirements of USP <788>

Additional testing was conducted to demonstrate:

- Maintenance of performance requirements after infusate exposure
- Luer connection performance
- Bag integrity (leakage)
- Performance after simulated shipping
- Shelf life
- SmartSite Microbial Ingress Testing

Conclusion
The information in this submission supports the safety and efficacy of the subject device for its intended use, and demonstrates substantial equivalence with the predicate device. The SmartSite™ Bag differences in materials, technology and operation from the predicate device do not raise new questions about safety and effectiveness.