December 6, 2024

Yukon Medical, LLC
℅ Prithul Bom
Final Reviewer
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K243486
Trade/Device Name: SmartSite™ Vented Vial Access Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: LHI
Dated: November 8, 2024
Received: November 8, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

David Wolloscheck, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243486

Device Name

20mm SmartSite™ Vented Vial Access Device

Indications for Use *(Describe)*

The 20mm SmartSite™ Vented Vial Access Device is intended for use by healthcare professionals, patients, and/or caregivers in a wide variety of healthcare and home use environments for reconstitution or dispensing of medication. The SmartSite Vented Vial Access Device is indicated for use with standard 20 mm rubber-stopper medication vials for reconstitution or dispensing of medications.

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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K243486 - 510(k) Summary

1. Submitter Information

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Date Summary Prepared:	December 6, 2024

2. Device Identification

Trade/Proprietary Name:	20mm SmartSite™ Vented Vial Access Device
Common Name:	Vial Access Device
Classification Name:	Intravascular Administration Set
Regulation Number:	21 CFR 880.5440
Class:	II
Classification Panel	General Hospital
Product Code:	LHI

3. Predicate Device

The SmartSite™ Vented Vial Access Device is substantially equivalent to the following predicate device:

Device Name	Manufacturer	510(k) Number	Date Cleared
SmartSite® Vented Vial Access Device	Yukon Medical, LLC	K151963	July 31, 2015

4. Device Description

The 20mm SmartSite™ Vented Vial Access Device is a stand-alone, sterile, single-use, disposable device which permits access to a medication vial without the use of a needle. It consists of a vial spike, the vial retention shroud, a hydrophobic filter assembly and a SmartSite™ needle-free valve.

The SmartSite™ Vented Vial Access Device is microbiologically closed. When used in a USP<797> compliant pharmaceutical compounding and storage environment, the SmartSite™ Vented Vial Access Device is capable of maintaining the sterility of vial medications for up to 7 days.

5. Intended Use/Indications for Use

Subject Device: 20mm SmartSite™ Vented Vial Access Device	Predicate Device: SmartSite® Vented Vial Access Device
The 20mm SmartSite™ Vented Vial Access Device is intended for use by healthcare professionals, patients, and/or caregivers in a wide variety of healthcare and home use environments for reconstitution or dispensing of medication. The SmartSite™ Vented Vial Access Device is indicated for use with standard 20 mm rubber-stopper medication vials for reconstitution or dispensing of medications.	The SmartSite® Vented Vial Access Device is intended for use by healthcare professionals in a wide variety of healthcare environments including hospitals, healthcare facilities, and pharmacies for reconstitution or dispensing of medication. The SmartSite® Vented Vial Access Device is indicated for use with rubber-stopper medication vials for reconstitution or dispensing of medications, including chemotherapy agents.

The 20mm SmartSite™ Vented Vial Access Device's intended use/indications for use is equivalent to that of the predicate device. Both the subject and predicate device are prescription only devices and are intended to be used with rubber-stopper medication vials for reconstitution or dispensing of medication. The subject device, in addition to its use by healthcare professionals in a variety of healthcare environments, is also indicated for use by patients and/or caregivers in home use environments. The subject device does not explicitly claim its use for the reconstitution or dispensing of chemotherapy agents as the home-users are not allowed to infuse or prepare chemotherapy agents by themselves, without the supervision of a healthcare professional.

Further, the subject device is identical to the predicate with no change to the design, construction, materials, technology and principle of operation. The performance specifications are identical between the two devices. The addition of intended users and the home environment does not significantly impact the safety and effectiveness of the device, as supported by the data collected from the human factors engineering/usability engineering studies that have been conducted and discussed in this 510(k) submission. The only difference between the two devices is in the

Instructions for Use which for the subject device incorporates a more detailed and easier way of interpreting the use of the device, targeting the lay users. No new questions about the safety or effectiveness for the subject device are arising. The purpose of the device remains the same i.e., use with rubber-stopper medication vials for reconstitution or dispensing of medications.

6. Predicate Device Comparison – Technical Characteristics

The subject device is identical to the predicate. Equivalency of technical characteristics and any differences between the SmartSite™ Vented Vial Access Device and the predicate device is demonstrated below.

Technical Characteristics	Device	
	Subject Device: 20mm SmartSite™ Vented Vial Access Device	**Predicate Device: SmartSite® Vented Vial Access Device**
Spike	Yes	Yes
Locking Shroud	Yes	Yes
Luer Access	SmartSite™ Needle-free Valve	SmartSite™ Needle-free Valve
Hydrophobic Filter	Yes	Yes

Design and Technology

Both the subject and the predicate device are designed using plastic and elastomeric materials and consist of a vial spike, the vial retention shroud, a hydrophobic filter assembly and a SmartSite needle-free valve.

- Vial Spike
  The spike is used to penetrate a standard medication vial stopper and provide path for fluid and filtered air.

  Both the subject and predicate devices have dual lumen spikes: one lumen for fluid and the other for filtered air that allows for pressure equalization.

- Locking Shroud/Retention Shroud
  The purpose of the locking shroud is to secure the device to a standard medication vial after the stopper is penetrated. Both the subject and predicate device utilize a locking shroud with retention tabs to ensure device security atop a vial.

- Luer Access
  Both the subject and predicate device use the same needle-free valve for luer access to the device: the SmartSite™ needle-free valve.

- Hydrophobic Filter
  Both the subject and predicate device use a hydrophobic filter membrane in their respective designs. This filter serves four purposes in both the devices:
  1) Prevents particulates from leaving the devices when air is introduced;
  2) Prevents contaminants in the surrounding environment from entering the secured drug vial;
  3) Prevents liquid from leaving the device during misuse conditions, where the devices are inverted when liquid is injected; and

4) Allows the air pressure in the vial to acclimate with ambient air pressure, preventing the build-up of pressure in the vial.

- SmartSite™ Needle-free Valve
  The SmartSite valve is manufactured by CareFusion Corporation, a BD (Becton, Dickinson and Company) company. The needle-free valve used in the subject device is identical to the one that was cleared under the predicate submission (K151963). However, the most recent 510(k) cleared for the same needle-free valve manufactured by CareFusion is 510(k)# K223088, the information from which is being leveraged for the review of the subject device.

Principle of Operation

Both the subject and the predicate device consist of a spike that a user centers on the stopper of a standard medication vial and pushes down, until the spike penetrates the stopper, and the shroud snaps in place. On injecting or withdrawing the fluid using a syringe or mating luer access device, the air and vapor in the vial gets displaced through the filter and into the surrounding environment. The air passes through the filter to maintain drug sterility, while equalizing pressure with the outside environment.

When used and stored in a USP<797> compliant pharmaceutical compounding environment, the device will allow the device to maintain the sterility of the vial contents for up to 7-days.

Materials

The subject device SmartSite™ Vented Vial Access Device is identical to the predicate and constructed of the same polymeric and elastomeric components. The main body of the device and the filter housing is molded from a Methyl Methacrylate Acrylonitrile Butadiene Styrene Copolymer (MABS), and a filter subassembly. The filter subassembly is comprised of a non-woven nylon substrate secured to a MABS housing. The filter housing is glued into the main body of the device using a Loctite medical grade UV adhesive.

A SmartSite™ needle-free access valve is bonded to the top of the main body using a Loctite medical grade UV adhesive. The SmartSite™ valve itself is comprised of a clear main body molded from Acrylic, a cap molded from Polyurethane, and a piston molded from Silicone. The piston is lubricated with Silicone oil.

The SmartSite™ Vented Vial Access Device materials do not contain natural rubber latex.

Both the subject and the predicate device have been tested to, and meet the biological requirements outlined in ISO 10993-1. More detailed information about the tests is provided in the Biocompatibility section of this submission.

7. Predicate Device Comparison – Performance Characteristics

The subject device is identical to the predicate with no changes to the design, geometry, technology, principle of operation, and materials. There is no change in the basic performance specifications of the subject device when compared to the predicate. Additional testing conducted including the testing to support the use of the device in home-use environments, in addition to its use in healthcare environments, are listed below:

- Human Factors Engineering/Usability Engineering Study
- Particulate Contamination Testing
- Fragmentation Testing

The testing for the following performance specifications were conducted previously for the predicate that apply in-full and are being leveraged for the subject device:

- Attachment force
- Filter resistant to misuse pressure
- Residual fluid volume
- Flow rate
- Packaging maintains sterile barrier
- Device packaging opens with gloved hands
- Packaging materials are radiation sterilizable
- Device materials are radiation sterilizable
- Vial septum visibility
- Device usable with gloved hands
- Priming volume
- SmartSite™ bond strength
- Stopper coring
- Device locks with >= 2 fingers
- Spike breakage
- Shroud breakage
- Vertical and horizontal detachment force
- Negative pressure leakage
- No leak, crack or rupture of device when subjected to positive misuse pressure
- Filter prevents >=99.9% particulates from exiting the vial
- Shelf life
- Storage temperature
- Chemotherapy and hazardous drug compatibility
- Device must maintain sterility of the drug in the vial for 7 days

Testing data for the SmartSite™ valve is being leveraged from 510(k) # K223088 application submitted by CareFusion Corporation.

8. Predicate Device Comparison – Chemical Characterization Testing

The predicate device was not tested for the chemical requirements however, the subject device is identical to the predicate with no changes in the chemical properties when compared to the predicate. The chemical requirement testing has been conducted with the subject device as per ISO 8536-4:2019 and ISO 8536-10:2015 at T=0 and T=3 yr timepoints to demonstrate that the acceptance criteria met all the chemical requirements for:

- Reducing Oxidizable Matter
- Metal Ions
- Titration for Acidity or Alkalinity
- Non-Volatile Residue
- UV Absorption

9. Predicate Device Comparison – Biocompatibility

The subject device is identical to the predicate and hence leverages the biocompatibility testing of the predicate. The predicate (with the exception of the SmartSite® needle-free valve) was assessed and tested for the below listed biological endpoints specified in ISO 10993-1.

- Cytoxicity by Elution Test (Cytotoxicity)
- Intracutaneous Reactivity (Irritation or Intracutaneous Reactivity)
- Maximization Test for Delayed Hypersensitivity (Sensitization)
- Acute Systemic Toxicity (Systemic Toxicity (Acute))
- Evaluation of Hemocompatibility: Interaction with Blood (Hemocompatibility)

The biocompatibility testing data for the SmartSite™ needle-free valve is being leveraged from that submitted under 510(k) # K223088 by CareFusion Corporation, a BD company.

Additional testing has been conducted for the following two biological endpoints for the entire subject device (including the SmartSite™ needle-free valve).

- Sub-acute Toxicity Testing
- Material-mediated Pyrogenicity Testing

10. Conclusion

Based on the comparison of the subject device's intended use, design, principle of operation and performance characteristics to the predicate device, the SmartSite™ Vented Vial Access Device is substantially equivalent to the previously cleared predicate device.