DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 31, 2015

Yukon Medical LLC
c/o Mr. Mark Job
Regulatory Technology Services, Inc.
1394 25th Street, NW
Buffalo, MN 55313

Re: K151963
Trade/Device Name: SmartSite® Vented Vial Access Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravenous Administration Set
Regulatory Class: II
Product Code: LHI
Dated: July 15, 2015
Received: July 16, 2015

Dear Mr. Job:

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 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" (21CFR 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 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 yours,

Tina Kiang
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for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications for Use Statement

510(k) Number (if known): K151963

Device Name: SmartSite® Vented Vial Access Device

Indications for Use:

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.

Prescription Use ___X_____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5. 510(k) Summary

5.1. Submitter Information

Company Name:	Yukon Medical, LLC
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Prepared By:	James Fentress, Director of Engineering Gilero, LLC 4022 Stirrup Creek Drive Suite 300 Durham, NC 27703 Phone: 919-595-8236 Fax: 919-595-8221 Email: jfentress@gilero.com
Date Summary Prepared:	February 18, 2015

5.2. Device Identification

Trade/Proprietary Name:	SmartSite® Vented Vial Access Device
Common Name:	Vial Access Device
Classification Name:	Intravascular Administration Set 21 CFR 880.5440, Class II
Classification Panel Product Code:	General Hospital LHI, I.V. Fluid Transfer Set

5.3. Predicate Device

The SmartSite® Vented Vial Access Device (SSVVAD) is substantially equivalent to the following
predicate device:

Device	Manufacturer	510(k)	Date Cleared
SmartSite® Vented Vial Access Device	Cardinal Health, Alaris Products	K052790	December, 23, 2005

5.4. 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 spike, locking shroud, hydrophobic filter, and SmartSite® needle-free access valve for Luer access.

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 to7 days.

5.5. Intended Use

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 standard rubber-stopper medication vials for reconstitution or dispensing of medications, including chemotherapy agents.

5.6. Predicate Device Comparison – Technical Characteristics

Equivalency of technical characteristics is demonstrated through a direct comparison of the Vented Single Vial Access Device and the predicate device listed in the table below.

The indications statement for the SmartSite® Vented Vial Access Device [Yukon Medical] is the same as its predicate device, Cardinal Health (Now CareFusion) SmartSite® Vented Vial Access Device (K052790).

Technical Characteristic	Device	
	Subject Device: [Yukon Medical] SmartSite® Vented Vial Access Device	Predicate Device: [CareFusion] 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

Spike
The spike is used to penetrate a standard medication vial stopper and provide fluid and filtered air paths.

The subject device and the predicate ([CareFusion] SmartSite® Vented Vial Access Device) both have equivalent dual lumen spikes; one lumen for fluid transfer and the other which allows for pressure equalization with vented air.

Locking 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
All configurations of the subject device and predicate device use the same needle free valve for Luer access to the device: the SmartSite® needle-free access 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 devices: 1) The filter prevents particulates from leaving the devices when air is introduced; 2) The filter prevents contaminants in the surrounding environment from entering the secured drug vial; 3) The filter prevents liquid from leaving the device during misuse conditions, where the devices are inverted when liquid is injected; 4) The filter allows the air pressure in the vial to acclimate with ambient air pressure, preventing the build-up of pressure in the vial.

Materials
The subject SmartSite® Vented Vial Access Device is constructed of polymeric 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 subject SmartSite® VVAD materials do not contain natural rubber latex.

The subject SmartSite® VVAD has been tested and meets the biological requirements outlined in ISO 10993-1.

5.7. Predicate Device Comparison – Performance Characteristics

The performance data supplied with this submission demonstrates that the subject SmartSite® VVAD meets all specified requirements and is substantially equivalent to the predicate device.

Since limited performance data for the predicate [CareFusion] SmartSite® Vented Vial Access Device was available, some performance characteristics of the predicate device were tested along with the subject SmartSite® VVAD.

The following tests were conducted on the predicate and subject SmartSite® Vented Vial Access Devices to demonstrate equivalency of the performance characteristics to the predicate device(s):

<u>Tests Performed on Subject and Predicate Devices:</u>

- Attachment Force
- Filter Misuse Pressure
- Residual Fluid Volume
- Flow Rate

<u>Tests Performed on Subject Device:</u>

- 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
- Filter prevents >=99.9%
- Shelf life (accelerated)
- Storage temperature
- Biocompatibility - ISO 10993
    - Cytotoxicity by Elution Test (Cytotoxicity)
    - Intracutaneous Reactivity (Irritation or Intracutaneous Reactivity)
    - Maximization Test for Delayed Hypersensivity (Sensitization)
    - Acute Systemic Toxicity (Systemic Toxicity (Acute))
    - Evaluation of Hemocompatibility: Interaction with Blood (Hemolysis)
- Chemotherapy and Hazardous Drug Compatibility

<u>Tests leveraged from Carefusion MAF-1918:</u>

- Needle-free Valve Activations >45
- Needle-free Valve ISO-594 Luer Compatibility
- Microbial ingress
- Leakage

Both the subject and predicate devices contain the SmartSite® needle free valve, which has been previously evaluated and cleared by the FDA for ISO-594 compliance, microbial ingress, leakage, and multiple/extended activation.

Additional testing on the subject SmartSite® VVAD has been done to ensure that the mechanically closed and microbiologically closed technical characteristics of the subject SmartSite® VVAD, not present on the predicate device, raise no new types of safety or effectiveness questions when compared to the predicate device.

- Maintains drug sterility for 7 days

5.8. Conclusion

Test results demonstrate that the SmartSite® Vented Vial Access Device is as safe and effective, and performs as well as the legally marketed device designated as the predicate device per 807.92 (b)(3).

Based on comparisons of the device's intended use, technology and performance characteristics, the subject SmartSite® VVAD is substantially equivalent to the indicated predicate device.