K132863

5. 510(k) Summary

5.1. Submitter Information

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OCT 0 4 2013

Date Summary Prepared: August 1, 2013

5.2. Device Identification

Trade/Proprietary Name: SmartSite® VialShield

Common Name: Vial Access Device

Classification Name: Intravascular Administration Set
21 CFR 880.5440, Class II

Classification Panel General Hospital
Product Code: LHI, I.V. Fluid Transfer Set

5.3. Predicate Device

The Closed Vial Access Device 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 SmartSite® VialShield 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® VialShield is indicated for use with rubber-stopper medication vials for reconstitution or dispensing of medications, including chemotherapy agents.

The SmartSite® VialShield is a mechanically closed device, designed to retain vapors produced from medications in the attached vial.

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

5.5. Intended Use

The SmartSite® VialShield 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® VialShield is indicated for use with rubber-stopper medication vials for reconstitution or dispensing of medications, including chemotherapy agents.

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

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 devices listed in the table below.

Technical Characteristic	Device	
	Subject Device: SmartSite® VialShield	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

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 (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® Vialshield device is constructed of polymeric components:

- Upper and Lower Housings: Polycarbonate

- Check Valves: Silicone
- Lubricant: Silicone
- Hydrophobic Filter Membrane: PTFE, Polyester
- Loctite 3341: UV adhesive
- Barrier Film: Polyether Polyurethane
- SmartSite® valve, including:
    - Body: Acrylic
    - Cap: Polyurethane
    - Piston: Silicone
    - Lubricants: Silicone

The subject SmartSite® Vialshield device is provided with a molded polyethylene cap, considered part of the packaging, made using low density polyethylene.

The subject SmartSite® Vialshield materials do not contain natural rubber latex.

The subject SmartSite® VialShield has been tested and meets the biological requirements outlined in ISO 10993-1. A summary of these test results is provided in Section 15 – Biocompatibility.

5.7. Predicate Device Comparison – Performance Characteristics

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

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

The following tests were conducted on the Vented Single Vial Access Device to demonstrate equivalency of the performance characteristics to the predicate device(s):

- Misuse Leak Test
- Filter Recovery Test (verification of hydrophobicity)
- Priming Volume
- Detachment Force (Horizontal)
- Detachment Force (Vertical)
- Priming Volume
- Filter Integrity
- Biocompatibility - ISO 10993 (SmartSite® VialShield tested only)
    - 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 (Hemocompatibility)
- Chemotherapy and Hazardous Drug Compatibility

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

Additional testing on the subject SmartSite® Vialshield has been done to ensure that the mechanically closed and microbiologically closed technical characteristics of the subject SmartSite® Vialshield, not present on the predicate device, raise no new concerns about the safety and efficacy when compared to the predicate device

- Expansion chamber air capture
- [device] retains introduced vapors
- Maintains drug sterility for 7 days (Approved protocol and acceptance criteria for the subject SmartSite® Vialshield only)

Test results demonstrate that the subject SmartSite® Vialshield is as safe and effective as the legally marketed devices designated as predicate device.

5.8. Conclusion

Test results demonstrate that the SmartSite® Vialshield is as effective, and performs at least as safely and effectively as the legally marketed devices designated as predicate devices.

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

Any differences between the SmartSite® Vialshield and the equivalent predicate devices have no significant influence on safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 4, 2013

Yukon Medical, LLC
Mr. Todd Korogi
President
2200 Gateway Centre Boulevard, Suite 208
MORRISVILLE NC 27560

Re: K132863
Trade/Device Name: SmartSite® VialShield
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: September 18, 2013
Received: September 19, 2013

Dear Mr. Korogi:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division 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): K132863

Device Name: SmartSite® VialShield

Indications for Use:

The SmartSite® VialShield 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® VialShield 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)

Richard C. Chapman
2013.10.03 13:52:58 -04'00'