DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
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October 3, 2017

Yukon Medical, LLC
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K172884
Trade/Device Name: Arisure™ Closed Vial Adapter
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI
Dated: December 8, 2016
Received: September 21, 2017

Dear Mark 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 (DICE) 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" (21 CFR 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 (DICE) 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,

Tara A. Ryan -S

for
Tina Kiang, PhD
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Arisure™ Closed Vial Adapter

Indications for Use *(Describe)*
The Arisure™ Closed Vial Adapter 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 Arisure™ Closed Vial Adapter is indicated for use with rubber-stopper medication vials for reconstitution or dispensing of medications, including chemotherapy agents.

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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5. 510(k) Summary

5.1. Submitter Information

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Date Summary Prepared: 25 August, 2017

5.2. Device Identification

Trade/Proprietary Name: 13mm Arisure™ Closed Vial Adapter
20mm Arisure™ Closed Vial Adapter
28mm Arisure™ Closed Vial Adapter

Common Name: Vial Adapter

Classification Name: Intravascular Administration Set

Regulation Number: 21 CFR 880.5440

Class: II

Classification Panel: General Hospital

Product Code: LHI, I.V. Fluid Transfer Set

5.3. Predicate Device

The Arisure Closed Vial Adapter is substantially equivalent to the following predicate device:

Device	Manufacturer	510(k)	Date Cleared
SmartSite® VialShield	Yukon Medical	K132863	October 4, 2013

5.4. Device Description

The Arisure Closed Vial Adapter 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 Arisure Closed Vial Adapter is indicated for use with rubber-stopper medication vials for reconstitution or dispensing of medications, including chemotherapy agents.

The Arisure Closed Vial Adapter is a mechanically closed device, designed to retain vapors produced from medications in the attached vial.

5.5. Intended Use

Arisure Closed Vial Adapter	Predicate Device
The Arisure™ Closed Vial Adapter 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 Arisure™ Closed Vial Adapter is indicated for use with rubber-stopper medication vials for reconstitution or dispensing of medications, including chemotherapy agents.	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 Arisure Closed Vial Adapter's intended use is equivalent to that of the SmartSite VialShield.

5.6. Indications for Use

Arisure Closed Vial Adapter	Predicate Device
The Arisure™ Closed Vial Adapter 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 Arisure™ Closed Vial Adapter is indicated for use with rubber-stopper medication vials for reconstitution or dispensing of medications, including chemotherapy agents.	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 Arisure Closed Vial Adapter's indications for use is equivalent to that of the SmartSite VialShield.

5.7. Predicate Device Comparison – Technical Characteristics

Equivalency of technical characteristics is demonstrated through a direct comparison of the Arisure Closed Vial Adapter device and the predicate devices listed in the table below.

Technical Characteristics	Subject Device: Arisure Closed Vial Adapter	Predicate Device: SmartSite® VialShield	Equivalence (Y/N)
Hydrophobic Filter	Yes	Yes	Y
Spike	Yes	Yes	Y
Locking Shroud	Yes	Yes	Y
Luer Access	Arisure Neutral Valve (ANV)	SmartSite® Needle Free Valve	Y
Materials (Fluid Contacting)	• Polycarbonate • Silicone • MABS	• Acrylic multipolymer • Silicone • Polycarbonate	Y

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 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 a needle free valve for luer access to the device.

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 Arisure Closed Vial Adapter device is constructed of polymeric components, of those components the following are fluid contacting:

- Arisure Closed Vial Adapter
  - Vial Adapter, Membrane Retention Ring, Bell Housing:
    Methyl Methacrylate Acrylonitrile Butadiene Styrene
  - Arisure Neutral Valve:
    Polycarbonate, Silicone, Fluorosilicone

The subject and predicate devices have been tested and meet the biological requirements outlined in ISO 10993-1.

5.8. Predicate Device Comparison – Performance Characteristics

The performance data supplied with this submission demonstrates that the Arisure Closed Vial Adapter meets all specified requirements and is substantially equivalent to the predicate device.

The following tests were conducted on the Arisure Closed Vial Adapter device to demonstrate equivalency of the performance characteristics to the predicate device(s):

- Misuse Test
- Detachment Force (Horizontal)
- Detachment Force (Vertical)
- Flow Rate
- Trapped Air Volume
- Residual Fluid
- Vial attachment force
- Vial pressure
- Valve Detachment Torque
- 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)
  - Materials Mediated Pyrogenicity
- Chemical Compatibility
- Sterile package integrity testing
- Distribution testing
- Shelf Life Testing

Note:
Both the subject and predicate devices contain needle free valves, which has been previously validated for ISO-594 compliance, microbial ingress, and multiple/extended activation.

5.9. Conclusion

Test results demonstrate that the Arisure™ Closed Vial Adapter is as safe, as effective, and performs as well as the legally marketed device designated as the predicate device.

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