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

September 29, 2017

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

Re: K172631
Trade/Device Name: Arisure™ Dry Spike
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI
Dated: October 13, 2016
Received: September 1, 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,

Tina Kiang, Ph.D.
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)*

K172631

Device Name
Arisure™ Dry Spike

Indications for Use *(Describe)*
The Arisure™ Dry Spike allows for the addition of liquid medications to IV containers through a needle-free access port, and serves as a connector between an IV container and a standard IV set, while minimizing exposure to drug aerosols and spills.

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: August 11, 2017

5.2. Device Identification

Trade/Proprietary Name: Arisure™ Dry Spike

Common Name: Infusion Access Device

Classification Name: Intravascular Administration Set

Regulation Number: 21 CFR 880.5440

Class: II

Classification Panel General Hospital

Product Code: LHI

5.3. Predicate Device

The Arisure™ Dry Spike is substantially equivalent to the following predicate device:

Device	Manufacturer	510(k)	Date Cleared
PhaSeal® Infusion Adapter	Carmel Pharma AB	K110023	04/12/2011

5.4. Device Description

The Arisure™ Dry Spike connects between IV containers and standard IV sets for the addition or removal of fluids. A needle-free valve on the side of the device provides a swab-able female access port for connection with ISO standard male luers. The needle-free valve provides an alternative fluid path to the IV container, which is normally accessed via a dedicated lumen within the spike. A pierceable septum distal to the device's spike, incorporates a redundant seal ring to minimize or eliminate fluid leakage that might otherwise occur during the spiking of IV containers. Fluid within the bag is then administered through a second, primary lumen within the spike. A third, vented lumen incorporates a check valve with hydrophobic vent media to equalize vacuum created within rigid containers and glass bottles during the administration of fluids.

The Arisure™ Dry Spike was designed to comply with ISO 8536-4:2010 as appropriate. The primary components of the Arisure Dry Spike include a vented lumen, handle, and needle-free valve, which are made of ABS, TPE, and PC/Silicone respectively. All materials were tested in accordance with ISO 10993-1.

5.5. Intended Use

Arisure™ Dry Spike	Predicate Device
The intended use of the Arisure™ Dry Spike is to allow the administration of a fluid from an IV container to a patient's vascular system through a needle or catheter inserted into a vein. The Arisure Dry Spike provides needle-free access to the infusion system through a female luer valve.	The intended use of this device is to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein.

The Arisure Dry Spike's intended use is equivalent to that of the PhaSeal Infusion Adapter.

5.6. Indications for Use

Arisure Dry Spike	Predicate Device
The Arisure™ Dry Spike allows for the addition of liquid medications to IV containers through a needle-free access port, and serves as a connector between an IV container and a standard IV set, while minimizing exposure to drug aerosols and spills.	The indication for use is admixing of drug into an IV container and administration/transfer of drug from the container to an external IV line, while minimizing exposure to potentially hazardous drugs aerosols and spills that can occur during admixing, administration and disposal process.

The Arisure™ Dry Spike's indications for use are equivalent to that of the PhaSeal Infusion Adapter.

5.7. Predicate Device Comparison – Technical Characteristics

Equivalency of technical characteristics are demonstrated through a direct comparison of the Arisure™ Dry Spike and the predicate device listed in the table below.

Technical Characteristic	Arisure™ Dry Spike	PhaSeal Infusion Adapter	Equivalence (Y/N)
Connections	• Rigid spike • Handle • Access port – needle-free	• Rigid spike • Handle • Access port – double membraned, sealed needle	Y
Materials	• Rigid spike: ABS • Handle: TPE • Access port: PC/Silicone • Spike cap: LDPE	• Rigid spike: ABS • Handle: TPE • Access port: ABS • Spike cap: PP	Y
Vent	• Third lumen for pressure equalization with check valve	• N/A	N

Same Technological Characteristics

Both the Arisure™ Dry Spike and PhaSeal Infusion Adapter have three connectors designed with the same use in mind. The rigid spikes' primary use is to pierce an IV container and are both made from ABS. The handles' primary use is to receive an external spike including an administration set, and they are both made from TPE. Both access ports aim to provide secure, safe access to the containers to which the device is connected to. Lastly, both spike caps add protection from the main spike when the device is not in use.

Different Technological Characteristics

A primary difference between the Arisure™ Dry Spike and the PhaSeal Infusion Adapter is that the latter does not have a vented lumen. This additional feature allows for pressure equalization when accessing rigid containers or glass bottles. This pressure equalization creates desirable fluid flow with these types of containers, especially when compared to non-vented alternatives such as the predicate device. This difference does not create an intended use different from the PhaSeal Infusion Adapter.

Another technical difference between the two devices is that the side port is needle-free for the Arisure™ Dry Spike and a double membraned, tightly sealed needle for the PhaSeal Infusion Adapter. Although the designs are different, both side ports have the same intended use. These differences between the devices do not raise different questions of safety and effectiveness.

5.8. Performance Testing

Non-clinical performance testing was performed to verify design requirements and to mitigate any potential risks. All testing was performed following maximum dose gamma irradiation sterilization to ensure the Arisure™ Dry Spike would still perform effectively

under the harshest potential sterilization. The following requirements were tested and completed with passing results.

Requirement ID	Bench Test Requirements
P1	**Flow Rate from IV Container** (per ISO 8536-4)
P2	**Flow Rate into IV Container** (per ISO 8536-4)
P3	**Air Leakage** (per ISO 8536-4)
P4	**Liquid Leakage** (per ISO 8536-4)
P5	**Bag Retention Force** (per ISO 8536-4)
P6	**Drip Chamber/IV Set Retention Force** (per ISO 8536-4)
P7	**Device Disassembly** (per ISO 8536-4)
P8	**Needle-free valve Detachment Torque** (Bond Strength)
P9	**Microbial Ingress**
N/A	**Leak Pressure Tolerance for Pre-slit Septa**

In addition to this bench testing biocompatibility testing, chemical testing, and package integrity testing was also conducted.

Requirement ID	Additional Testing
C2	**Biocompatibility**
C3	**Sterilization**
C7	**Chemical Compatibility**
E1	**Shelf Life**
E2	**Distribution Testing**

For Biocompatibility the following tests from IS0-10993 were tested and completed with passing results:

- Cytotoxicity – ISO MEM Elution L-929 Mouse Fibroblast Cells
- Reactivity – ISO Intracutaneous Irritation Test
- Sensitization – ISO Maximization Sensitization – Extraction Methodization Test
- Systemic Toxicity (Acute) – ISO Acute Systemic Toxicity Test
- Hemocompatibility – ASTM Method Hemolysis Test – Extraction Method
- Pyrogen – ISO Materials Mediated Rabbit Pyrogen Testing

For Package Integrity the following tests were completed in accordance with or satisfying the requirements for the following standards:

- ISTA P2A (2011)
- ASTM D4169-14 Standard Practice for Performance Testing of Shipping Containers and Systems DC-13
- ASTM F88M-09 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F2096-11 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)

- ASTM F1886 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

5.9. Conclusion

Based on thorough comparison to the predicate device and performance testing, we have concluded that the Arisure Dry Spike is substantially equivalent to the previously cleared predicate device.