March 2, 2021

Yukon Medical, LLC
Pamela Mcnulty
Sr. Director QA and Compliance
4021 Stirrup Creek Dr Ste 200
Durham, North Carolina 27703

Re: K201422
Trade/Device Name: Arisure Closed System Drug Transfer Device (CSTD)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: November 25, 2020
Received: December 2, 2020

Dear Pamela Mcnulty:

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. 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 located 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.

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

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 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,

for Payal Patel
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201422

Device Name
Arisure Closed System Drug Transfer Device (CSTD)

Indications for Use *(Describe)*
Arisure® is a Closed System Drug Transfer Device (CSTD) that mechanically prohibits the release of drugs in vapor, aerosol or liquid form during preparation and administration, and prevents the introduction of microbial and airborne contaminants into the drug or fluid path, allowing the system to minimize exposure of individuals, healthcare personnel, and the environment to hazardous drugs.

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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510(k) Summary

I. SUBMITTER

Yukon Medical, LLC
4021 Stirrup Creek Drive, Suite 200
Durham, NC 27703
Phone: 919-595-8250
Fax: 919-595-8251
Contact Person: Pam McNulty
Sr. Director QA and Compliance

Date Prepared: March 2nd, 2020

II. DEVICE

Name of Device: Arisure® Closed System Drug Transfer Device (CSTD)
Common Name: Drug Reconstitution and Transfer System
Classification Name: Intravascular Administration Set
Regulation Number: 21 CFR 880.5440
Regulatory Class: II
Product Code: ONB

III. PREDICATE DEVICE

Name of Predicate: TEVADAPTOR® Closed Drug Reconstitution and Transfer System
Predicate 510(k) Number: K141448
Regulation Number: 21 CFR 880.5440
Product Code: ONB
This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Arisure® Closed System Drug Transfer Device (CSTD) uses three primary components to prevent the escape of drug and ingress of microbes: Closed Vial Adapter, Closed Male Luer, and Dry Spike. The Closed Vial Adapter attaches to the drug vial allowing access to the vial contents while preventing vial pressurization by capturing displaced vapor and allowing filtered air into the vial. The Dry Spike attaches to an IV container allowing drug to be injected into the container while a separate port accepts the spike of an administration set. The Closed Male Luer syringe adapter provides a means of closed fluid transfer from the drug vial to the IV container. The Closed Male Luer was designed specifically to access the needle-free valve (neutral valve) on the Closed Vial Adapter and Dry Spike. The fluid path of the Closed Vial Adapter, Dry Spike, and Closed Male Luer is normally closed, opening only when the Closed Male Luer is connected to the neutral valve.

V. INDICATIONS FOR USE

Arisure® is a Closed System Drug Transfer Device (CSTD) that mechanically prohibits the release of drugs in vapor, aerosol or liquid form during preparation and administration, and prevents the introduction of microbial and airborne contaminants into the drug or fluid path, allowing the system to minimize exposure of individuals, healthcare personnel, and the environment to hazardous drugs.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A direct comparison of the indications for use and technical characteristics between the subject and predicate devices demonstrates equivalency. Minor differences between subject and predicate device characteristics do not introduce different questions of safety or effectiveness, the subject device is substantially equivalent to the predicate device.

	Subject Device (K201422)	Predicate Device (K141448)	Discussion
Indications for Use	Arisure® is a Closed System Drug Transfer Device (CSTD) that mechanically prohibits the release of drugs in vapor, aerosol or liquid form during preparation and administration, and prevents the introduction of microbial and airborne contaminants into the drug or fluid path, allowing the system to minimize exposure of individuals, healthcare personnel, and the environment to hazardous drugs.	TEVADAPTOR is a Closed System Drug Transfer Device (CSTD) that mechanically prohibits the release of the drug in vapor, aerosol or liquid form during preparation and administration, and prevents the introduction of microbial and airborne contaminants into the drug or fluid path, allowing the system to minimize exposure of individuals, healthcare personnel, and the environment to hazardous drugs	Same
Design	Designed using plastic and elastomeric materials, has normally closed fluid path which closes off flow when the device is not attached to mating component. Includes anti-unwinding feature.	Designed using plastic, elastomeric, and metal materials, has normally closed fluid path which closes off flow when the device is not attached to mating component.	Minor differences in materials do not raise different questions of safety or effectiveness as all materials contain inherent properties to achieve their intended use and have been demonstrated to be biocompatible.
External Dimensions (LxW) (inches)	Closed Male Luer: 1.1 x 0.6 Closed Vial Adapter: 2.5 x 2.25 Dry Spike: 4.0 x 0.5	Syringe Adaptor: 2.2 x 0.6 Vial Adaptor: 2.2 x 0.9 Spike Port Adaptor: 8.5 x 0.8	External dimensions have no impact on performance and do not raise different questions of safety or effectiveness.
Packaging	Form, fill, seal packaging with top web material sealed to bottom web material	Form, fill, seal packaging with top web material sealed to bottom web material	Same
Sterilization	Gamma Irradiation	EO	Both sterilization methods are considered traditional by FDA and both achieve a SAL of 10^{-6}, no different questions of safety or effectiveness.

Latex	Not made with natural rubber latex	Not made with natural rubber latex	Same
Pyrogenicity	Non-pyrogenic	Non-pyrogenic	Same
Reuse	Single use	Single use	Same
Shelf Life	3 years	3 years	Same
Biocompatibility	Externally communicating Blood contact, indirect Prolonged duration (>24 hours to 30 d)	Externally communicating Blood contact, indirect Prolonged duration (>24 hours to 30 d)	Same
Flow Rate	≥76 mL/min	125 mL/min	This discrepancy is due to the fact that the subject device is limited by the CML which was designed to have the flow rate of an 18-gauge needle. This was based upon clinical input prior to the device design and this difference is not anticipated to have any impact on safety and efficacy.
Residual Fluid	<0.05mL for 13 mm and 20mm <1mL for 28 mm	0.37mL for 20mm	The residual fluid is less than the predicate, no different questions of safety or effectiveness
Priming Volume	0.12 mL for Dry Spike, 0.11mL for 13mm, 0.10mL for 20mm 0.12mL for 28mm ACVA	0.15mL	The priming volume is less than the predicate, no different questions of safety or effectiveness
	Subject Device (K201422) Closed Male Luer	**Predicate Device (K141448) Syringe Adaptor**	**Discussion**
Connector Type	Luer Lock	Luer Lock	Minor differences in materials due to different components achieving the same intended use.
Septum/Seal Type	Flat, Split Septum	Double Seal	
Upper Housing	Polycarbonate	ABS	
Lower Housing	Polycarbonate	Polycarbonate	
Cannula	Polycarbonate	Stainless Steel	
Anti-Unwinding Housing	Polycarbonate	N/A	
Piston	Silicone	Stainless Steel	
Actuator	COC	N/A	
Lubrication	Fluorosilicone	N/A	
Adhesive	Acrylic Adhesive	Acrylic Adhesive	

	Subject Device (K201422) Closed Vial Adapter with Neutral Valve	Predicate Device (K141448) Vial Adaptor / Luer Lock Adaptor	Discussion
Vial Adapter	Terlux 2802	ABS	Minor differences in materials due to different components achieving the same intended use.
Bell Base	Cyrolite CG97	N/A	
Bell Labyrinth Ring	Cyrolite CG97	N/A	
Bell Housing	Terlux 2822	N/A	
Bell Membrane	Medalist MD145	N/A	
Bell Membrane UV Tracer	SC-5	N/A	
Membrane Retention Ring	Terlux 2802	N/A	
Vent Filter Membrane	ePTFE Membrane with polyester support	Charcoal	
Bell Filter Membrane	ePTFE Membrane with polyester support	N/A	
Vent Check Valve	Elastosil LR3043 60	N/A	
Bell Check Valve	Silicone	N/A	
Adhesive	Acrylic Adhesive	N/A	
Check Valve Lubrication	Silicone	N/A	
Neutral Valve/Luer Lock Adaptor Housing	Polycarbonate	ABS	
Neutral Valve/Luer Lock Adaptor Piston	Silicone	Polyisoprene	
Neutral Valve/Luer Lock Adaptor Retention Ring	Polycarbonate	Polyisoprene	
Neutral Valve/Luer Lock Adaptor Lubrication	Fluorosilicone, Trifluoroprophyl-methylsiloxane	N/A	

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Test Name	Standard #
Cytotoxicity	ISO 10993-5
Hemocompatibility	ISO 10993-4
Sensitization	ISO 10993-10
Systemic Toxicity (Acute)	ISO 10993-11
Irritation	ISO 10993-10
Material-Mediated Pyrogenicity	ISO 10993-11
LAL Endotoxin	ANSI/AAMI ST72:2002, USP 24<161>
Luer Access	ISO 594-2
Liquid Leakage (back pressure)	ISO 594-2
Liquid Leakage (connected pressure)	ISO 594-2
Ease of Assembly	ISO 594-2
Resistance to Overriding	ISO 594-2
Stress Cracking	ISO 594-2
Separation Force	ISO 594-2
Gloved Hands	N/A, to verify the device is usable with nitrile gloved hands
Valve Removal Torque and Bond Strength	N/A, >4.5 in-lbs
Vial Pressure	N/A
Attachment Force	N/A, <40 lbf
Horizontal / Vertical Detachment	N/A, remain attached with a 15N force attached for 15 seconds
Misuse Leakage	N/A, no leakage with 7.5PSI for 15 seconds
Coring	N/A, coring of the drug vial septum to have particulates does not occur
Security of Attachment	N/A, remain attached without leak with a 15N load for 15 seconds
Drug/Device Compatibility	N/A
Dry Disconnection	N/A
Microbial Ingress	N/A
Particulate	USP 788
Vapor Study	CDC-2015-0075, NIOSH -288:2015 (draft)
Chemical Characterization	ISO 10993-18
Toxicological Risk Assessment	ISO 10993-17
Sub-Acute Toxicity	ISO 10993-11
Partial Simulation Performance Tests	ISTA P2A (2011)
Standard Practice for Performance Testing of Shipping Containers and Systems	ASTM D4169-14
Standard Test Method for Seal Strength of Flexible Barrier Materials	ASTM F88M-09
Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)	ASTM F2096-11
Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection	ASTM F1886

VIII. CONCLUSIONS

The non-clinical data demonstrate that the subject device is substantially equivalent and performs comparably to the predicate device currently marketed with some minor differences. These differences do not impact the intended use or the fundamental scientific technology of the device. Through the comprehensive performance testing performed the subject device has demonstrated substantial equivalence to the predicate.