March 21, 2025

Yukon Medical, LLC
Pam McNulty
Sr. Director QA and Compliance
4021 Stirrup Creek Drive
Suite 200
Durham, North Carolina 27703

Re: K240761
Trade/Device Name: Arisure® Closed Male Luer with Spike Adapter (YM060)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: LHI
Dated: February 20, 2025
Received: February 21, 2025

Dear Pam 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Porsche Bennett
For David Wolloscheck, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240761

Device Name

Arisure® Closed Male Luer with Spike Adapter (YM060)

Indications for Use *(Describe)*

The Arisure® Closed Male Luer with Spike Adapter serves as a connector between an IV container and a standard IV set.

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 – K240761

1. Submitter Information

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Prepared By:	Mahima Gupta, Regulatory Affairs & Compliance Specialist Yukon Medical, LLC Phone: 857-999-6865 Fax: 919-595-8251 Email: mgupta@yukonmedical.com
Date Summary Prepared:	March 20, 2025

2. Device Identification

Trade/Proprietary Name:	Arisure® Closed Male Luer with Spike Adapter (YM060)
Common Name:	N/A
Classification Name:	Intravascular Administration Set
Regulation Number:	21 CFR 880.5440
Class:	II
Classification Panel	General Hospital
Product Code:	LHI

3. Predicate Device

The Arisure® Closed Male Luer with Spike Adapter is substantially equivalent to the following predicate device:

Device	Manufacturer	510(k) Number	Date Cleared
Closed Male Luer	Yukon Medical, LLC	K171101	June 2, 2017

4. Reference Device

The Arisure® Closed Male Luer with Spike Adapter uses the following reference device:

Device	Manufacturer	510(k) Number	Date Cleared
SmartSite™ Bag	Yukon Medical, LLC	K201936	May 6, 2021

5. Device Description

The Arisure Closed Male Luer with Spike Adapter, also referred to as Arisure CML with Spike Adapter or CML with Spike Adapter, is an extension of the predicate device, i.e., Closed Male Luer. The primary components of the CML with Spike Adapter include: a Closed Male Luer, a Male Luer Lock Connector, and an Extended Spike Adapter.

The subject device allows for administration set preservation when administering multiple drug therapies to the same patient. It provides a needle-free, drip-free connection between an IV bag or a rigid container and an IV administration set. The CML side provides a luer lock connection to a Bag Spike with Neutral Valve. It also gives the user a drip-free disconnect when needing to use multiple bags or bottles for the infusion. The Spike Adapter side allows for a secure connection to any ISO standard IV spike. An IV administration set can be connected safely and securely to the device through a pierceable septum.

The CML with Spike Adapter is designed to comply with ISO 8536-4:2019 as appropriate.

6. Intended Use

Subject Device: Arisure Closed Male Luer with Spike Adapter	Predicate Device: Closed Male Luer
The Arisure® Closed Male Luer with Spike Adapter is a single use, sterile, non-pyrogenic, swab-able, bi-directional valve intended for use as an accessory to an Intravascular Administration Set. It allows for the administration of fluids from a container to a patient's vascular system through the administration needle or catheter which is inserted into the vein or artery.	The Closed Male Luer (CML) is a single use, sterile, non-pyrogenic, swab-able, bi-directional valve intended for use as an accessory to an Intravascular Administration Set. The Closed Male Luer provides access for the administration of fluids from a container to a patient's vascular system through the administration needle or catheter which is inserted into the vein or artery.

The Arisure Closed Male Luer with Spike Adapter's intended use is equivalent to that of the predicate device. Both devices are intended for administration of fluids from a container to a patient's vascular system through the administration needle or catheter which is inserted into the vein or artery.

7. Indications for Use

Subject Device: Arisure Closed Male Luer with Spike Adapter	Predicate Device: Closed Male Luer
The Arisure® Closed Male Luer with Spike Adapter serves as a connector between an IV container and a standard IV set.	The Closed Male Luer (CML) is a single use, sterile, non-pyrogenic, swab-able, bi-directional valve intended for use as an accessory to an Intravascular Administration Set. The Closed Male Luer provides access for the administration of fluids from a container to a patient's vascular system through the administration needle or catheter which is inserted into the vein or artery.

Both the subject and the predicate devices are indicated to be used as an accessory to an Intravascular Administration Set for the handling of and administration of fluids from a container to a patient's vascular system through the administration needle or catheter which is inserted into the vein or artery. Hence, Arisure Closed Male Luer with Spike Adapter's indications for use is equivalent to that of the predicate device.

8. Predicate Device Comparison – Technical Characteristics

Equivalency of technical characteristics and any differences between the Arisure Closed Male Luer with Spike Adapter and the predicate device is demonstrated below.

List of Components

The subject device is an extension of the predicate. The components constituting the two devices are listed below:

Closed Male Luer (predicate)

- Lower housing/inner luer
- Upper housing/male body
- Actuator
- Piston/Pre-slit silicone rubber seal
- Cannula
- Anti-unwinding housing

Arisure Closed Male Luer with Spike Adapter (subject device)

- Closed Male Luer (identical to the predicate)
- Male Luer Lock Connector
- Extended Spike Adapter

The subject device is an extension of the predicate, with the Closed Male Luer portion of the device identical to the predicate. The additional components of the subject device provide the means for a liquid to flow through the device and a connection to ISO 8536-4 compliant standard IV set spikes. Though this constitutes a minor difference in the technological characteristics, it does not impact the intended use of the device, its overall functionality, or the principle of operation significantly, when compared to the predicate. No safety or effectiveness is being impacted.

Design

Both the subject and the predicate device are designed using plastic and elastomeric materials and have normally closed valves at the CML end which close off flow when the devices are not attached to female luers or female valves.

The primary difference in the design of the two devices is that the subject device is an extension of the predicate. The Arisure CML with Spike Adapter consists of an Extended Spike Adapter connected to the CML via a Male Luer Lock Connector.

Deployment Method

Both the subject and the predicate device are attached in the same way to a mating connection at the CML end and have normally closed valves which prevent flow until attached to a female luer or valve on an intermediate device for delivery or withdrawal of fluids to/from a patient.

For the subject device, the primary difference lies at the distal end of the device that is composed of a pierceable septum that mates with ISO 8536-4 standard IV set spikes. When pierced, the septum seals around the IV set spike to eliminate fluid leakage and forms a secure connection.

Principle of Operation

Both the subject and the predicate device use an elastomeric component at the CML end to act as a spring in tension which is placed in a high-energy state when attached to a female luer or female valve. The movement of the elastomeric portion of either valve causes a fluid pathway to open, permitting the delivery or withdrawal of fluid through the valve. When the CML is removed from the female luer or female valve, the high-energy state of the elastomeric component moves the valve back into the relaxed, closed position. Both use the restoring force of the spring to restore the valve to the normally closed position.

For the subject device, at the distal end of the device lies a pierceable septum that mates with ISO 8536-4 standard IV set spikes. When the exposed septum is pierced by an ISO 8536-4 IV set spike, the septum seals around the IV set spike to eliminate fluid leakage that might occur during the spiking process. Once the IV set spike forms a secure connection with the spike adapter and the CML is connected to a female luer device, the fluid path is open. This constitutes a minor difference when compared to the predicate, however, it does not impact the intended use of the device or its overall functionality significantly. No safety or effectiveness is being impacted.

Materials

The subject device Arisure Closed Male Luer with Spike Adapter is constructed of the following materials:

- Closed Male Luer (predicate): Polycarbonate, Silicone, Cyclic Olefin Copolymer, Fluorosilicone, and Acrylic Adhesive.
- Male Luer Lock Connector: Polycarbonate
- Extended Spike Adapter: PVC
- Adhesive: Acrylic Adhesive
- Solvent Bonding: MEK/Cyclohexanone

The CML portion of the subject device is constructed of the exact same materials as the predicate CML. The materials of the two additional components (i.e., Male Luer Lock Connector and Extended Spike Adapter) making up the subject device are commonly used in the medical device industry. No novel or custom resin or other material formulations have been used in this device, nor is it manufactured, processed, or distributed in a manner that is novel or unique.

Both the Arisure CML with Spike Adapter and the predicate have passed biocompatibility testing in accordance with ISO 10993 standards.

Shelf-life

The shelf-life for the subject device has been tested for and determined to be of three (3) years, as opposed to the predicate's one (1) year shelf-life. Aged, packaged parts underwent the appropriate testing with acceptable results to support this claim. No safety or effectiveness is impacted.

Though there is a difference in the shelf-life duration across the subject and the predicate devices, the difference does not raise any issues of safety and effectiveness for the subject device, as the primary concern and requirement is for the packaging to be labelled correctly.

The following standards apply or have been used for the subject device, in part or in full, or as a reference, as appropriate.

- ASTM D4169-22 - Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM D4332-22 – Standard Practice for Conditioning Containers Packages or Packaging Components for Testing
- ASTM F1980-21 - Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F2096-11 (2019) – Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ASTM F88/F88M-21 - Standard Test Method for Seal Strength of Flexible Barrier Materials
- ISO 11607-1: 2019/Amd 1: 2023 – Packaging for terminally sterilized medical devices - Part 1: Requirements for materials sterile barrier systems and packaging systems [Including Amendment 1 (2023)]
- ISO 11607-2: 2019 – Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming sealing and assembly processes
- ASTM F1886/F1886M-16 – Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F2054-13 (20) - Standard Test Method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization Within Restraining Plates
- ISTA P2A-98 (2011) - Partial Simulation Performance Tests: 2A Packaged products weighing 150lb or less
- ISO 8536-4: 2019 – Infusion equipment for medical use – Part 4: Infusion sets for single use gravity feed
- ISO 80369-7: 2021 – Small bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications (ISO 80369-7:2021)
- IEC 62366-1: 2020 – Medical devices – Part 1: Application of usability engineering to medical devices
- ISO 22413: 2021 – Transfer sets for pharmaceutical preparations: Requirements and test methods
- ISO 15747: 2018 – Plastic containers for intravenous injections

- ISO 15223-1: 2021 – Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

Sterilization Method

The Arisure Closed Male Luer with Spike Adapter (subject device) is sterilized via E-beam irradiation, achieving a Sterility Assurance Level (SAL) of 10^{-6}. The predicate on the other hand, is sterilized via Gamma irradiation, achieving an SAL of 10^{-6}.

Both the devices are packaged sterile and undergo sterilization via irradiation methods categorized as "Established Category A" having a long history of safe and effective use. Both the methods help achieve an SAL of 10^{-6} with no different questions being raised about their safety or effectiveness.

The following standards apply or have been used for the subject device, in part or in full, or as a reference, as appropriate.

- EN ISO 14937: 2009 - Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
- SS-EN 556-1:2001/AC:2006 – Sterilization of medical devices – Requirements for medical devices to be designated 'STERILE' – Part 1: Requirements for terminally sterilized medical devices
- ISO 11137-1: 2006/Amd 2: 2018 – Sterilization of health care products - Radiation - Part 1: Requirements for development validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2013) and Amendment 2 (2018)]
- SS-EN ISO 11137-2: 2015 – Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)
- ISO 11137-3: 2017 – Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development validation and routine control
- EN ISO 11737-1: 2018/Amd 1: 2021 - Sterilization of medical devices - Microbiological methods - Part1: Determination of a population of microorganisms on products (ISO 11737-1:2006/Cor1:2007)
- ISO 11737-2: 2020 – Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition validation and maintenance of a sterilization process
- ISO 14644-1: 2015 – Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
- ISO 14644-2: 2015 – Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration

Packaging

Both the Arisure Closed Male Luer with Spike Adapter and the predicate use a form, fill, seal (FFS) packaging that includes the top web material sealed to the bottom web material.

The following standards apply or have been used for the subject device, in part or in full, or as a reference, as appropriate.

- ASTM D4169-22 - Standard Practice for Performance Testing of Shipping Containers and Systems

- ASTM D4332-22 – Standard Practice for Conditioning Containers Packages or Packaging Components for Testing
- ASTM F1980-21 - Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F2096-11 (2019) – Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ASTM F88/F88M-21 - Standard Test Method for Seal Strength of Flexible Barrier Materials
- ISO 11607-1: 2019/Amd 1: 2023 – Packaging for terminally sterilized medical devices - Part 1: Requirements for materials sterile barrier systems and packaging systems [Including Amendment 1 (2023)]
- ISO 11607-2: 2019 – Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming sealing and assembly processes
- ASTM F1886/F1886M-16 – Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F2054-13 (20) - Standard Test Method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization Within Restraining Plates
- ISTA P2A-98 (2011) - Partial Simulation Performance Tests: 2A Packaged products weighing 150lb or less
- ISO 15223-1: 2021 – Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

9. Predicate Device Comparison – Performance Characteristics

The non-clinical performance data stated in this submission along with that submitted with the 510(k) of the predicate device demonstrates that the subject device meets all specified requirements and is substantially equivalent to the predicate. Wherever applicable, the performance testing data of the predicate device has been leveraged for the subject device. The following tests were completed with passing results:

- Device Flow Rate
- Leakage
- Separation Force
- Detachment Force
- Assembly Strength
- Multiple Activations
- Extended Activations
- Dry Disconnection
- Microbial Ingress
- Particulates
- Chemical Compatibility
- Shelf-Life Testing
- Distribution Testing
- Package Performance Testing
- Package Stability Testing

The following standards apply or have been used for the performance testing of subject device, in part or in full, or as a reference, as appropriate.

- ISO 8536-4: 2019 – Infusion equipment for medical use – Part 4: Infusion sets for single use gravity feed
- ISO 80369-7: 2021 – Small bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications (ISO 80369-7:2021)
- IEC 62366-1: 2020 – Medical devices – Part 1: Application of usability engineering to medical devices
- ISO 22413: 2021 – Transfer sets for pharmaceutical preparations: Requirements and test methods
- ISO 15747: 2018 – Plastic containers for intravenous injections

Valve States
The valve state at the CML end of both the devices during usage and rest are identical. The valves are closed during rest, and open upon the connection of the male luer end to a female luer or valve.

Mechanical Performance
The devices have been assessed for leakage under pressure, separation force, detachment force, flow rate, assembly strength, activations (multiple and extended), dry disconnection, microbial ingress and other relevant performance testing. Wherever applicable, the performance data of the predicate device has been leveraged for the subject device.

Disinfectable (Microbiologically Closed)
Both the subject and predicate device can be disinfected using 70% isopropanol.

Chemical Compatibility
Both the subject and predicate device were tested against chemicals with characteristics known to be of issue with the polymeric components used in their construction to ensure compatibility.

10. Use of Reference Device – Performance Characteristics

To support and to provide as a substantiation of the functional performance and characteristics of the Extended Spike Adapter portion of the subject device, SmartSite™ Bag (K201936) was used as a reference device. The reference device was tested to the applicable sections of ISO 15747: 2018 (Plastic container for intravenous injections). The subject device was tested to the same standard and evaluated for the below applicable performance specifications:

- Penetration ability of the septum of access port
- Impermeability of the septum of access port
- Adhesion strength of the infusion device

11. Biocompatibility

In accordance with ISO 10993-1, the Arisure CML with Spike Adapter and the predicate device are both categorized as below:

- Category: External communicating device
- Contact: Blood path, indirect
- Contact duration: “B” Prolonged (>24 hours to 30 days)

The subject device, like the predicate, has been evaluated for biocompatibility appropriate to the contact characterization (type and duration), in accordance with the requirements of ISO 10993-1: 2018(E). Specific testing included:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Material Mediated Pyrogenicity
- Acute Systemic Toxicity
- Sub-Acute Toxicity
- Hemocompatibility

The following standards apply or have been used for the biocompatibility testing of subject device, in part or in full, or as a reference, as appropriate.

- ISO 10993-1: 2018 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-10: 2021 – Biological evaluation of medical devices – Part 10: Tests for skin sensitization
- ISO 10993-11: 2018 – Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
- ISO 10993-12: 2021 - Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
- ISO 10993-4: 2017 - Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
- ISO 10993-5: 2009 - Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 14971: 2019 – Medical devices – Application of risk management to medical devices

12. Sterilization Validation

The Arisure Closed Male Luer with Spike Adapter is sterilized using e-beam irradiation in accordance with a validated sterilization cycle. The following standards were referenced during the sterilization validation process:

- ISO 11137-1 Sterilization of Healthcare Products-- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 11137-2 Sterilization of healthcare products-- Radiation -- Part 2: Establishing the sterilization dose
- ISO 11737-1:2018/Amd 1:2021 Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products – Amendment 1
- AAMI/ANSI/ISO TIR13004:2013/R:2016 – Sterilization of health care products – Radiation – Substantiation of a selected sterilization dose: Method $VDmax^{SD}$

13. Conclusion

Based on the comparison of the subject device's intended use, design, technology and performance characteristics to the predicate device, the Arisure Closed Male Luer with Spike Adapter is substantially equivalent to the previously cleared predicate device.