July 9, 2026

MedSource Labs, LLC
Emilie Andrews
Regulatory and Quality Compliance Engineer
8600 Shelby Ct. Suit 100
Chanhassen, Minnesota 55317

Re: K260539
Trade/Device Name: MedSource QuickSafe™ Safety IV Catheter; MedSource PurSafe™ Safety IV Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: June 8, 2026
Received: June 9, 2026

Dear Emilie Andrews:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

DAVID WOLLOSCHECK -S

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.*

510(k) Number *(if known)*
K260539

Device Name
MedSource QuickSafe™ Safety IV Catheter; MedSource PurSafe™ Safety IV Catheter

Indications for Use *(Describe)*
The MedSource PurSafe 1.V. Safety Catheter, and the MedSource QuickSafe I.V. Safety Catheter are indicated to be inserted into the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravascularly. The catheters may be used intravascularly with power injectors at a maximum pressure of 325 psi with a Luer lock connection only

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 -K260539

*Prepared in accordance with 21 CFR 807.92*

Date Prepared: July 8, 2026

## 1. Submitter

MedSource Labs, LLC

8600 Shelby Court, Suite 100

Chanhassen, MN 55317, USA

Phone: 800-876-8264

Contact: Emilie Andrews, Regulatory Affairs

## 2. Device Identification

Trade Names: MedSource QuickSafe™ Safety IV Catheter; MedSource PurSafe™ Safety IV Catheter

Common Name: IV Catheter / Safety IV Catheter

Classification Name: Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days

Regulation Number: 21 CFR 880.5200

Product Code: FOZ

Device Class: II

## 3. Predicate Device

B. Braun Introcan Safety® 2 IV Catheter, cleared under K213664 (February 11, 2022).

## 4. Device Description

The MedSource PurSafe™ and QuickSafe™ Safety IV Catheters are sterile, single-use, over-the-needle peripheral intravascular catheters incorporating an integrated passive safety mechanism designed to reduce the risk of accidental needlestick injury. Each device consists of a stainless-steel introducer needle attached to a transparent needle hub and a flexible catheter with a radiopaque strip attached to a color-coded catheter hub. The safety mechanism is integrated within the catheter hub and automatically covers the needle tip upon withdrawal, preventing needle exposure after use.

PurSafe™ Model: Includes a metal locking clip positioned inside the catheter hub. As the needle is retracted, it passively engages the clip, securing it over the needle tip and providing protection from accidental exposure.

QuickSafe™ Model: Functionally identical to PurSafe™ in clinical use and performance. The only design difference is an additional plastic housing that fully encloses the metal locking clip, providing an extra protective barrier without altering device function, performance, or handling. Selection between models is a matter of user/institutional preference (e.g., cost, purchasing standardization) and does not reflect a difference in intended use, safety, or effectiveness.

The devices are supplied sterile, non-pyrogenic, and intended for single use only. Sterilization is performed using ethylene oxide (EO) gas to a Sterility Assurance Level (SAL) of $10^{-6}$. The devices are latex-free.

The MedSource PurSafe™ and QuickSafe™ Safety IV Catheters are available in four gauge sizes, color-coded per ISO 10555-5 (18G Green, 20G Pink, 22G Blue, 24G Yellow), and in both PUR and PTFE catheter tube material variants, for a total of sixteen model configurations (Table 1).

## 5. Indications for Use

The MedSource PurSafe I.V. Safety Catheter, and the MedSource QuickSafe I.V. Safety Catheter are indicated to be inserted into the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravascularly. The catheters may be used intravascularly with power injectors at a maximum pressure of 325 psi with a Luer lock connection only.

## 6. Contraindications

- Do not use this device for power injection without verifying a secure Luer lock connection.
- Product should not be used for administration of high viscosity fluids.
- Do not use in patients weighing less than 5 kg (11 lb); the device has not been evaluated against the first 24-hour EO/ECH sterilant residual exposure limit applicable to patients below this weight.

## 7. Device Specifications

Table 1 lists the sixteen model configurations covered by this submission, spanning four gauge sizes, two catheter tube materials (PUR and PTFE), and the two device families. All configurations are of the Standard (non-winged) design.

| Model No. | Trade Name | Catheter Material | Gauge | Catheter Length | Hub Color |
|---|---|---|---|---|---|
| MS-88118 | QuickSafe Safety IV Catheter | PUR | 18G | 45 mm | Green |
| MS-88120 | QuickSafe Safety IV Catheter | PUR | 20G | 32 mm | Pink |
| MS-88122 | QuickSafe Safety IV Catheter | PUR | 22G | 25 mm | Blue |
| MS-88124 | QuickSafe Safety IV Catheter | PUR | 24G | 19 mm | Yellow |
| MS-88218 | QuickSafe Safety IV Catheter | PTFE | 18G | 45 mm | Green |
| MS-88220 | QuickSafe Safety IV Catheter | PTFE | 20G | 32 mm | Pink |
| MS-88222 | QuickSafe Safety IV Catheter | PTFE | 22G | 25 mm | Blue |
| MS-88224 | QuickSafe Safety IV Catheter | PTFE | 24G | 19 mm | Yellow |
| MS-89118 | PurSafe Safety IV Catheter | PUR | 18G | 45 mm | Green |
| MS-89120 | PurSafe Safety IV Catheter | PUR | 20G | 32 mm | Pink |
| MS-89122 | PurSafe Safety IV Catheter | PUR | 22G | 25 mm | Blue |
| MS-89124 | PurSafe Safety IV Catheter | PUR | 24G | 19 mm | Yellow |
| MS-89318 | PurSafe Safety IV Catheter | PTFE | 18G | 45 mm | Green |
| MS-89320 | PurSafe Safety IV Catheter | PTFE | 20G | 32 mm | Pink |
| MS-89322 | PurSafe Safety IV Catheter | PTFE | 22G | 25 mm | Blue |
| MS-89324 | PurSafe Safety IV Catheter | PTFE | 24G | 19 mm | Yellow |

The following specifications are common to all sixteen configurations listed in Table 1:

Needle material: AISI 304 stainless steel.

Needle hub material: PP Copolymer.

Catheter hub (holder) material: POM (Polyoxymethylene).

Radiopaque strip: Barium sulfate, co-extruded and fully enclosed within the catheter tube wall.

Sharps injury protection mechanism: Passive, stainless steel snap-fit locking clip (AISI 302/305); engages the needle externally upon withdrawal of the needle hub; the needle is not retracted into the catheter body; no spring or elastic component; no user action required to activate.

QuickSafe-specific feature: An additional PP Copolymer external housing (Body with Projection) encloses the locking clip. This housing does not alter device function, performance, or handling and is not present on PurSafe.

Sterilization: Ethylene oxide (EO), Sterility Assurance Level (SAL) of $10^{-6}$.

Packaging: Dual-layer Tyvek/soft PP-PE film peel pouch.

Use: Sterile, single-use, non-pyrogenic, latex-free.

## 8. Technological Characteristics Comparison to Predicate

Table 2 compares the technological characteristics of the subject devices to the predicate device, the B. Braun Introcan Safety® 2 IV Catheter (K213664).

| **Device Characteristic** | **Subject Device** | **Predicate Device** | **Similarity** |
|---|---|---|---|
| Device name | QuickSafe & PurSafe Safety IV Catheters | Introcan Safety® 2 IV Catheter | N/A |
| Sponsor | MedSource Labs, USA | B. Braun, USA | N/A |
| 510(k) reference | This submission (K260539) | K213664 | N/A |
| Regulation no. | 21 CFR 880.5200 | 21 CFR 880.5200 | Same as predicate |
| Regulation name | Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days | Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days | Same as predicate |
| Product code | FOZ | FOZ | Same as predicate |
| Date cleared | This submission | February 11, 2022 | N/A |
| Device description | A range of over-needle peripheral intravascular catheters intended for intravenous administration of fluids, blood sampling, or the monitoring of vital signs, such as blood pressure. | A range of over-needle peripheral intravascular catheters intended for intravenous administration of fluids, blood sampling, or the monitoring of vital signs, such as blood pressure. | Same as predicate |
| Indications for use | The MedSource PurSafe™ IV Safety Catheter, and the MedSource QuickSafe™ IV Safety Catheter are indicated to be inserted into the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravascularly. The catheters may be used intravascularly with power injectors at a maximum | The Introcan Safety® 2 IV Catheter is inserted into a patient's vascular system for short term use to sample blood, monitor blood pressure, or administer fluids and blood intravascularly. The catheters may be used intravascularly with power injectors at a maximum pressure of 300 psi with a Luer lock connection only. | Same as predicate |

| Device Characteristic | Subject Device | Predicate Device | Similarity |
|---|---|---|---|
| | pressure of 325 psi with a Luer lock connection only. | | |
| Principle of operation | The needle is inserted to gain vascular access. Blood fills the flashback chamber. After placement, the needle is removed from the catheter, leaving the catheter behind for vascular access. Once the needle is removed, the safety mechanism activates and the needle is locked. | The needle is inserted to gain vascular access. Blood fills the flashback chamber. After placement, the needle is removed from the catheter, leaving the catheter behind for vascular access. Once the needle is removed, the safety mechanism activates and the needle is locked. | Same as predicate |
| Catheter range design | Conventional IV single lumen catheter design with no integral extension tubing. Catheter hub does not include wings. Septum with one-time blood control. | Conventional IV single lumen catheter design with no integral extension tubing. Catheter hub includes wings and no-wings options. Septum with one-time blood control. | Same as predicate |
| Catheter size range and flow rate | 24G x 19 mm – 18 mL/min; 22G x 25 mm – 33 mL/min; 20G x 32 mm – 55 mL/min; 18G x 45 mm – 85 mL/min. | 24G x 19 mm – 22 mL/min; 24G x 14 mm; 22G x 25 mm – 35 mL/min; 20G x 50 mm – 55 mL/min; 20G x 32 mm; 20G x 25 mm; 18G x 45 mm – 100 mL/min; 18G x 32 mm. | Different from predicate — see Note 1 |
| Color coding | According to ISO 10555-5 | According to ISO 10555-5 | Same as predicate |
| Winged hub option | No | Yes | Different from predicate — see Note 2 |
| Blood control design | Yes | Yes | Same as predicate |
| Sharps injury protection | Passive mechanism with slide needle shielding | Passive mechanism with slide needle shielding | Same as predicate — see Note 3 |
| Catheter tube material | Polyurethane (PUR) and Polytetrafluoroethylene (PTFE) | Polyurethane (PUR) and Polytetrafluoroethylene (PTFE) | Same as predicate |
| Catheter tip shape | Beveled | Beveled | Same as predicate |
| Needle material | Stainless steel | Stainless steel | Same as predicate |
| X-ray visible | Barium sulphate strip in catheter tube | Barium sulphate strip in catheter tube | Same as predicate |
| Labeled for single use? | Yes | Yes | Same as predicate |
| Sterility | Terminally sterilized, SAL $10^{-6}$ | Terminally sterilized, SAL $10^{-6}$ | Same as predicate |
| Sterilization method | Ethylene oxide (EO) | Ethylene oxide (EO) | Same as predicate |
| Shelf life | 4 years | 1 year | Different from predicate — see Note 4 |

| Device Characteristic | Subject Device | Predicate Device | Similarity |
|---|---|---|---|
| Power injector compatible | Yes, up to 325 psi with Luer lock only | Yes, up to 300 psi with Luer lock only | Different from predicate — see Note 5 |
| Biocompatibility | Biocompatible in accordance with ISO 10993 series and FDA guidance | Biocompatible in accordance with ISO 10993 series and FDA guidance | Same as predicate |
| MR compatibility | MR not evaluated | MR Conditional | Different from predicate — see Note 6 |
| Environment of use | Rx Only | Rx Only | Same as predicate |

Note 1: The subject device offers a smaller choice of catheter lengths across the same gauge sizes than the predicate device, although the exact gauge/length combinations offered are available in both the subject and predicate ranges. The lack of certain specific gauge/length combinations does not raise additional questions of safety or effectiveness. Flow rates for both devices are similar across the gauge/length range and within the acceptance limits specified in ISO 10555-1, with no additional issues of safety or effectiveness being raised.

Note 2: The predicate device offers each gauge/length combination in both a wingless and winged design, whereas the subject device offers only a wingless design. This does not affect the performance data for the catheter, so no additional issues of safety or effectiveness are raised.

Note 3: The PurSafe™ and QuickSafe™ models utilize the same fundamental sharps injury protection mechanism as the predicate, consisting of a passive mechanism that shields the needle upon withdrawal without requiring user activation. The additional plastic housing in the QuickSafe™ model fully encloses the clip but does not alter the mechanism's design, deployment, or function. This does not raise different questions of safety or effectiveness.

Note 4: The subject device offers a verified shelf life longer than the predicate, with no additional issues of safety or effectiveness being raised.

Note 5: The subject device is labeled for power injection up to 325 psi, while the predicate device is labeled up to 300 psi. Typical clinical use occurs at or below 300 psi; the higher-pressure rating of the subject device is an additional design margin confirmed by performance testing, not a change in intended use, operating principle, or clinical application. This does not raise different questions of safety or effectiveness.

Note 6: The predicate device is labelled as ‘MR Conditional’ while the subject device is labelled as ‘MR not evaluated’, with no additional issues of safety or effectiveness being raised.

Conclusion: The subject and predicate devices have the same indications for use and fundamental technological characteristics. The differences identified in Table 2 do not raise different questions of safety or effectiveness. The performance and biocompatibility data summarized in Sections 9 and 10 demonstrate that the subject device is substantially equivalent to the predicate device.

## 9. Summary of Non-Clinical Performance Data

The following non-clinical testing was conducted to support substantial equivalence:

- Sterilization validation: Ethylene oxide sterilization per ISO 11135:2014, with product adoption into an existing validated cycle assessed per AAMI TIR28:2016/(R)2024 Annex A.

- EO/ECH sterilant residuals: Tested per ISO 10993-7:2008/AMD 1:2019. Results comply with the neonate prolonged-exposure limits; use in patients weighing less than 5 kg is contraindicated (Section 6).
- Bioburden: Tested per ISO 11737-1; all results within the NMT 25 CFU/device acceptance criterion.
- Bacterial endotoxin (BET): Tested by the LAL gel-clot method; results below the 20 EU/device acceptance criterion, confirmed as a routine lot-release test.
- Particulate matter: Tested per USP <788>, Method 1 (Light Obscuration Particle Count Test), on finished, traceable device configurations.
- Sharps injury protection: Tested per ISO 23908:2024 (Sections 6.26–6.29) across all gauges for both device families; 300 samples per test per device, zero failures, satisfying C95/R99.
- Mechanical performance: Catheter-hub retention (pull force), effective length, corrosion resistance, kink resistance, and simulated use tested per ISO 10555-1:2023, at time zero and following accelerated aging; zero failures across tested configurations.
- Radiopacity: Tested per ASTM F640-23 on both PUR and PTFE catheter tube materials; catheter shaft visible under fluoroscopy in all samples tested.
- Post-market surveillance / risk management: MAUDE data for the Product Code FOZ device family were reviewed and incorporated into the risk management file per ISO 14971:2019; reported catheter material integrity events were attributable to user error, and reported safety-mechanism events are not applicable to the subject devices' passive mechanism design.

## 10. Biocompatibility

Per ISO 10993-1:2018, the MedSource QuickSafe and PurSafe Safety IV Catheters are classified, based on the worst-case body-contacting components, as follows:

Contact type: External communicating device, circulating blood.

Contact duration: Prolonged contact (> 24 hours to ≤ 30 days).

Representative samples were selected using a worst-case approach (smallest and largest gauge sizes, with colored components from intermediate gauges), and cytotoxicity testing was additionally performed on aged samples to evaluate the effect of shelf-life aging. Table 3 lists each biological endpoint evaluated, the applicable test standard, the performing laboratory study identifier, and the result obtained.

| **Biological Endpoint** | **Test Standard** | **Study ID (Test Facility)** | **Result** |
|---|---|---|---|
| Cytotoxicity (MEM Elution) | ISO 10993-5 | QQU032-CY40 (NAMSA) | Non-cytotoxic. Grade 0 at 24 and 48 hours; test article extract met the requirements of the test. |
| Sensitization (Guinea Pig Maximization) | ISO 10993-10 | QQU018-SE01 (NAMSA) | Not considered a sensitizer. No evidence of delayed dermal contact sensitization. |
| Irritation / Intracutaneous Reactivity | ISO 10993-23 | QQU017-IR01 (NAMSA) | Met requirements. Overall mean score difference (test vs. control): 0.0 (NS extract), 0.3 (SSO extract); requirement is ≤ 1.0. |
| Acute Systemic Toxicity | ISO 10993-11 | QQU019-ST10 (NAMSA) | No mortality or evidence of systemic toxicity. Each test article extract met the requirements of the study. |

| Biological Endpoint | Test Standard | Study ID (Test Facility) | Result |
|---|---|---|---|
| Material-Mediated Pyrogenicity | ISO 10993-11 (USP <151>) | QQU020-ST01 (NAMSA) | Met USP requirements for absence of pyrogens. No animal showed a temperature rise ≥ 0.5°C. |
| Subacute / Subchronic Systemic Toxicity | ISO 10993-11 | QQU025-ST25 (NAMSA) | Parenteral administration of the test article extract did not produce systemic toxicity in rats. |
| Hemocompatibility — Hemolysis (ASTM F756) | ISO 10993-4 | QQU021-HE03 (NAMSA) | Direct contact: slightly hemolytic (2.30%). Extract: non-hemolytic (1.05%). Both results met the requirements of the test. |
| Hemocompatibility — Complement Activation (SC5b-9) | ISO 10993-4 | QQU022-HE32 (NAMSA) | Non-activator of the complement system. |
| Hemocompatibility — Partial Thromboplastin Time | ISO 10993-4 | QQU023-HE50 (NAMSA) | Met the requirements of the test (ASTM F2382). |
| Hemocompatibility — Platelet and Leukocyte Count | ISO 10993-4 | QQU024-HE42 (NAMSA) | Met the requirements of the test. Platelet count 93.1% and leukocyte count 99.0% of vehicle control. |
| Genotoxicity — Bacterial Reverse Mutation (Ames) | ISO 10993-3 | QQU033-GE01 (NAMSA) | Non-mutagenic in all five tester strains, with and without metabolic activation. |
| Genotoxicity — Mouse Lymphoma Assay | ISO 10993-3 | QQU034-GE12 (NAMSA) | Non-mutagenic. Mutant frequency did not exceed the Global Evaluation Factor in the presence or absence of metabolic activation. |
| Implantation (Local Effects) | ISO 10993-6 | QQU031-IM01 (NAMSA) | Minimal or no reaction. Test Article Relative Score of -2.3 (category range 0.0-2.9). |

All completed biocompatibility tests met their respective acceptance criteria. Consistent with ISO 10993-1:2018, which permits either a chemistry-driven (ISO 10993-18) or a traditional biological response-based testing approach, MedSource selected the biological response-based approach; the comprehensive endpoint coverage in Table 3, together with the established use history of the device materials, supports that no additional chemical characterization testing is necessary to demonstrate biological safety.

## 11. Conclusion

The performance, biocompatibility, and sterilization data summarized in this 510(k) Summary demonstrate that the MedSource QuickSafe™ and PurSafe™ Safety IV Catheters are as safe and effective as, and substantially equivalent to, the predicate device, the B. Braun Introcan Safety® 2 IV Catheter (K213664). The identified technological differences do not raise different questions of safety or effectiveness.

Supporting Documentation:

Biological Evaluation Report — MedSource PurSafe and QuickSafe Safety IV Catheters (ISO 10993-1:2018).

NAMSA Final Study Reports: QQU032-CY40, QQU018-SE01, QQU017-IR01, QQU019-ST10, QQU020-ST01, QQU025-ST25, QQU021-HE03, QQU022-HE32, QQU023-HE50, QQU024-HE42, QQU033-GE01, QQU034-GE12, QQU031-IM01.

Attachment 1a: AAMI TIR28 Product Adoption and Process Equivalence Report.

Attachment 3a: EO/ECH Residual Testing per ISO 10993-7:2008/AMD 1:2019.

Attachment 4b: Bacterial Endotoxin Test Work Instruction and results.

Attachment 6: Particulate Matter Testing per USP <788>.

Attachment 7: Device Physical Equivalence Justification.

Attachment 8b: ISO 23908:2024 Sharps Injury Protection Test Report.

Attachment 9c: ASTM F640-23 Radiopacity Test Report.

Attachment 9d: Simulated Use and Kink Resistance Test Data.

Attachment 10a–10e: Risk Management Plan, Design Comparison, Pull Force Test Report, Root Cause/CAPA Documentation.