July 10, 2026

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

Re: K261041
Trade/Device Name: ClearSafe Closed System
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: June 11, 2026
Received: June 12, 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261041

Please provide the device trade name(s).

ClearSafe Closed System

Please provide your Indications for Use below.

The ClearSafe Closed System is 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

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Prepared in accordance with 21 CFR 807.92

Date Prepared: July 9, 2026

1. Submitter

MedSource Labs, LLC

8600 Shelby Court, Suite 100

Chanhassen, MN 55317, USA

Phone: 952 241 8332

Contact: Emilie Andrews, Regulatory and Quality Compliance Engineer

2. Device Identification

Trade Name: ClearSafe Closed System

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

Classification Name: Intravascular catheter

Regulation Number: 21 CFR 880.5200

Product Code: FOZ

Device Class: II

510(k) Number: K261041 (this submission)

3. Predicate Device

Trade Name: BD Nexiva™ Closed IV Catheter System

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

Classification Name: Intravascular catheter

Regulation Number: 21 CFR 880.5200

Product Code: FOZ

Device Class: II

510(k) Number: K243403

Sponsor: Becton, Dickinson and Company (BD)

4. Device Description

The ClearSafe Closed System is 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. The device is designed to provide protection for healthcare workers against accidental needlestick injury and exposure to parts of the device that have come into contact with patient's blood or other body fluids.

The indwelling polyurethane (PUR) catheter tubing has radio-opaque stripes down its length to allow visibility under x-ray. The catheter range includes both single and dual port options. The single port models have a single proximal connection point — a female Luer lock — secured to the proximal end of polyvinyl chloride (PVC) tubing attached to the catheter hub. The dual port models have two proximal connection points via a Y-connector at the end of the PVC tubing: an identical female Luer lock, and a second female Luer lock fitted with a removable needleless Luer-activated valve (LAV).

The ClearSafe Closed System is comprised of a sharp needle attached to a needle hub held within a catheter hub, which is also attached to the PVC tube. The catheter hub is hollow, allowing the needle to be withdrawn inside using an activation slide mechanism after initial insertion. Once the needle is fully withdrawn, an audible click confirms it is safely locked inside the catheter body, leaving the catheter inserted in the patient for continued vascular access. The safety mechanism is active (user-activated) and does not use springs or elastic components.

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

The ClearSafe Closed System is available in four gauge sizes, color-coded per ISO 10555-5 (18G Green, 20G Pink, 22G Blue, 24G Yellow), in both single-port and dual-port configurations, for a total of eight model configurations. Design specifications for each device model, including gauge size and catheter length, are provided in Table 1.

Table 1: Device Specifications

Model No.	Trade Name	Port Configuration	Gauge	Catheter Length	Hub Color
MS-87218	ClearSafe Closed System	Single Port	18G	1.25 in (32 mm)	Green
MS-87220	ClearSafe Closed System	Single Port	20G	1.25 in (32 mm)	Pink
MS-87222	ClearSafe Closed System	Single Port	22G	1.00 in (25 mm)	Blue
MS-87224	ClearSafe Closed System	Single Port	24G	0.75 in (19 mm)	Yellow
MS-87318	ClearSafe Closed System	Dual Port	18G	1.25 in (32 mm)	Green
MS-87320	ClearSafe Closed System	Dual Port	20G	1.25 in (32 mm)	Pink
MS-87322	ClearSafe Closed System	Dual Port	22G	1.00 in (25 mm)	Blue
MS-87324	ClearSafe Closed System	Dual Port	24G	0.75 in (19 mm)	Yellow

Catheter length is measured as the nominal effective length from the hub connection to the distal tip, per HHPL-QC-TMP-35. Dual port models share identical gauge, catheter length, and hub color specifications with their single port counterparts and differ only in the addition of a Y-connector and needleless Luer-activated valve (LAV) on the second proximal port.

The following specifications are common to all eight configurations listed in Table 1: Needle material — stainless steel; Catheter hub material — polycarbonate (PC); Catheter tube material — polyurethane (PUR) with barium sulfate radiopaque stripe; Sharps injury protection mechanism — active, user-activated slide needle shield with audible lock confirmation; no spring or elastic component. Sterilization: ethylene oxide (ETO), SAL of 10^{-6}. Use: sterile, single-use, non-pyrogenic.

5. Indications for Use

The ClearSafe Closed System is 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.

7. Technological Characteristics Comparison to Predicate

Table 2 compares the technological characteristics of the subject device to the predicate device, the BD Nexiva™ Closed IV Catheter System (K243403).

Table 2: Technological Characteristics Comparison

Device Characteristic	Subject Device	Predicate Device	Similarity
Device name	ClearSafe Closed System	BD Nexiva™ Closed IV Catheter System	N/A
Sponsor	MedSource Labs, LLC	Becton, Dickinson and Company (BD)	N/A
510(k) Number	This submission (K261041)	K243403	N/A
Regulation no.	21 CFR 880.5200	21 CFR 880.5200	Same as predicate
Regulation name	Intravascular catheter	Intravascular catheter	Same as predicate
Product code	FOZ	FOZ	Same as predicate
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 ClearSafe Closed System is 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.	Indicated to be inserted into a patient's peripheral vascular system for short term use to sample blood, monitor blood pressure, or administer fluids. May be used for any patient population with consideration given to adequacy of vascular anatomy and duration of therapy. 22-18 GA (0.9-1.3 mm) devices suitable for use with power injectors set to a maximum of 300 psi (2068 kPa) when access ports not suitable for power injection are removed.	Substantially equivalent to predicate
Principle of operation	Closed peripheral intravascular catheter system with integrated extension set incorporating a single port or Y (dual)-port injection site.	Closed peripheral intravascular catheter system with integrated extension set incorporating a single port or Y (dual)-port injection site. Incorporates Instaflash™ needle technology to assist with flashback visualization.	Substantially equivalent to predicate
Catheter configurations	Single Port; Dual Port	Single Port; Single Port with MaxZero™; Dual Port with Q-Syte™; Dual Port with Q-Syte™ and End Cap; Dual Port with MaxZero™	Substantially equivalent to predicate – see Note 2
Y-site / injection port	Y-connector to second female Luer port (dual port models only)	Y-connector to second port (dual port models); Q-Syte™ needleless connector on select configurations	Substantially equivalent to predicate – see Note 2

Device Characteristic	Subject Device	Predicate Device	Similarity
Needleless valve	Removable needleless Luer-activated valve (LAV) on dual port models	Q-Syte™ needleless connector / MaxZero™ valve on select dual port configurations	Substantially equivalent to predicate – see Note 2
Gauge sizes offered	18G, 20G, 22G, 24G	18G, 20G, 22G, 24G	Same as predicate
Catheter length by gauge	24G x 0.75 in; 22G x 1.00 in; 20G x 1.25 in; 18G x 1.25 in	24G x 0.56 in; 22G x 0.75 in; 20G x 1.00 in; 18G x 1.25 in; 1.75 in (extended length option)	Different from predicate – see Note 1
Color coding	According to ISO 10555-5	According to ISO 10555-5	Same as predicate
Winged hub option	Yes	Yes	Same as predicate
Blood control design	Yes	Yes	Same as predicate
Sharps injury protection	Active mechanism with slide needle shielding	Passive mechanism with needle shielding	Different from predicate – see Note 3
Catheter tube material	Polyurethane (PUR)	Polyurethane (PUR)	Same as predicate
Catheter tip shape	Beveled	Not specified in predicate 510(k) summary	Unable to compare to predicate – see Note 4
Needle material	Stainless steel	Stainless steel	Same as predicate
X-ray visible	Barium sulfate stripe in catheter tube	Barium sulfate stripe in catheter tube	Same as predicate
Labeled for single use?	Yes	Yes	Same as predicate
Sterilization method	Ethylene oxide (ETO)	Ethylene oxide (ETO)	Same as predicate
Shelf life	2 years	3 years	Different from predicate – see Note 5
Power injector compatible	Yes, up to 325 psi with Luer lock connection only	Yes; 22-18 GA (0.9-1.3 mm) devices suitable for use with power injectors set to a maximum of 300 psi (2068 kPa) when access ports not suitable for power injection are removed	Substantially equivalent to predicate
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	Not specified in predicate 510(k) summary	Unable to compare to predicate – see Note 6
Environment of use	Rx Only	Rx Only	Same as predicate

Note 1: The subject and predicate devices include the same standard gauge sizes (18G, 20G, 22G, and 24G) commonly used for peripheral intravascular access. While minor differences in catheter length are present, and the predicate offers an additional 1.75 in extended-length option not offered by the subject device, these variations fall within clinically accepted ranges and do not impact the intended use, insertion technique, or performance characteristics of the device. Therefore, these differences do not raise new questions of safety and effectiveness.

Note 2: The subject device's dual port models use a Y-connector with a removable needleless Luer-activated valve (LAV), while the predicate offers a broader range of connector options, including Q-Syte™ and MaxZero™ needleless valves, across its dual port configurations. Both approaches provide closed, needle-free access to the fluid pathway consistent with the intended use, and the difference in specific connector technology does not raise new questions of safety and effectiveness.

Note 3: Both the subject and predicate devices incorporate engineered sharps injury protection features to reduce the risk of needlestick injury after catheter use. The predicate device uses a passive safety mechanism, while the subject device utilizes an active safety mechanism requiring user activation. This represents a different design approach to achieving the same safety objective and does not alter the intended use or fundamental scientific technology. Active safety mechanisms are well-established in legally marketed devices and are consistent with sharps injury prevention principles outlined in the Needlestick Safety and Prevention Act. Risks associated with user activation have been mitigated through device design, labeling, and human factors validation testing. Therefore, this difference does not raise new questions of safety and effectiveness.

Note 4: The subject device includes a beveled catheter tip, while the predicate device tip geometry is not specified in the publicly available 510(k) summary. Beveled catheter tips are a standard design feature for peripheral intravenous catheters and are widely used to facilitate insertion. This characteristic does not represent a new or different technological approach and does not raise new questions of safety and effectiveness.

Note 5: The subject device has a labeled shelf life of 2 years, compared to 3 years for the predicate device. Shelf life is supported by stability and packaging validation testing in accordance with applicable standards. The difference in shelf life does not affect the device's intended use, performance, or safety profile and therefore does not raise new questions of safety and effectiveness.

Note 6: The predicate device does not include MR compatibility information in its 510(k) summary. The subject device has not been evaluated for MR safety and does not include MR-specific labeling. Neither device includes MR compatibility claims. Therefore, this does not represent a difference in technological characteristics and does not raise new questions of safety and effectiveness.

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 data summarized in Section 8 demonstrate that the subject device is substantially equivalent to the predicate device.

8. Summary of Non-Clinical Performance Data

Nonclinical performance testing was conducted to support substantial equivalence and to demonstrate that the subject intravascular catheter with integrated safety mechanism performs as intended and is as safe and effective as the predicate device. Testing encompassed mechanical, functional, dimensional, connector, and sharps injury protection evaluations representative of clinical use conditions. Worst-case configurations, including smallest gauge sizes, maximum length assemblies, and aged samples (to account for sterilization and shelf life), were evaluated as applicable.

Mechanical and fluid pathway integrity: assessed through tensile force, burst pressure, liquid and air leakage, flow rate, and power injection performance testing. Results confirmed that the catheter assemblies maintain structural integrity, leak resistance, and required flow performance under simulated clinical conditions, meeting all predefined acceptance criteria.

Dimensional and physical characterization: effective length, inner and outer diameters, distal tip geometry, surface finish, and corrosion resistance were verified. All attributes met design specifications and applicable standard requirements.

Needle and safety mechanism performance: needle point quality, catheter-to-needle alignment, hub bonding strength, safety clip interaction, activation force, override resistance, free-fall resistance, and post-activation sharps accessibility were evaluated. Testing demonstrated reliable activation, secure needle containment, and effective sharps injury prevention consistent with the intended safety function.

Connector performance: tested in accordance with small-bore connector standards, including stress cracking, pressure and sub-atmospheric leakage, axial separation, resistance to unscrewing and overriding, disconnection torque, and air leakage assessments. Results demonstrated secure, leak-free connections compatible with clinical infusion systems.

Testing was performed in accordance with FDA-recognized consensus standards, including ISO 10555-1, ISO 10555-5, ISO 23908, and ISO 80369-7, or equivalent validated internal methods where appropriate. All results met predefined acceptance criteria with no failures observed. Clinical testing was not required, as bench testing was sufficient to demonstrate comparable technological characteristics and performance to the predicate device. Based on the totality of evidence, the subject device supports a determination of substantial equivalence.

9. Biocompatibility

This Biological Evaluation Report (BER) was conducted in accordance with FDA-recognized international standard ISO 10993-1:2018, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process." Based on the intended use and the worst-case body-contacting components, the ClearSafe Closed System is classified as an external communicating device with direct and indirect contact with circulating blood, of prolonged duration (>24 hours to <30 days).

Representative samples for biocompatibility testing were selected using a worst-case approach, including the smallest and largest gauge sizes and colored components from intermediate gauges to account for potential colorant-related risks; samples were sterilized twice to represent worst case. Cytotoxicity testing was additionally performed on aged samples to assess the potential impact of material degradation and leachables over the labeled shelf life; all other endpoints were evaluated on fresh, representative samples.

In accordance with ISO 10993-1:2018 and FDA guidance, the following biological endpoints were considered relevant for this device type and were addressed through direct biological testing:

Cytotoxicity (ISO 10993-5:2009); Sensitization (ISO 10993-10:2021); Irritation or Intracutaneous Reactivity (ISO 10993-23:2021); Acute Systemic Toxicity (ISO 10993-11:2017); Subacute/Subchronic Toxicity (ISO 10993-11:2017); Hemocompatibility (ISO 10993-4:2017), comprising hemolysis (extract and direct contact), complement activation assay, partial thromboplastin time, and platelet and leukocyte count assay; Material-mediated Pyrogenicity (ISO 10993-11:2017); Genotoxicity (ISO 10993-3:2014), comprising bacterial reverse mutation and lymphoma assay; and Muscle implantation (ISO 10993-6:2016).

A traditional biological response-based testing approach was selected in lieu of chemical characterization under ISO 10993-18, consistent with the flexibility permitted by ISO 10993-1:2018. This approach was considered adequate because all relevant biological endpoints were addressed through direct biological testing on the finished, sterilized device, capturing real-world exposure conditions including any extractables, leachables, degradation products, processing residues, or sterilization residuals; all completed tests met their respective acceptance criteria; and the device materials have an established history of use in similar medical applications.

Results of this testing demonstrate that the ClearSafe Closed System does not elicit unacceptable cytotoxic, sensitization, irritation, systemic toxicity, hemocompatibility, or other adverse biological responses under the specified conditions of use. Based on the totality of evidence — materials of construction, nature and duration of patient contact, manufacturing and sterilization processes, and biocompatibility test results — the ClearSafe Closed System is considered biocompatible and suitable for its intended clinical use.