September 15, 2023

MedSource International LLC
Emilie Andrews
Quality and Regulatory Compliance Engineer
8600 Shelby Court, Suite 100
Chanhassen, Minnesota 55317

Re: K223788
Trade/Device Name: The MedSource TrueSafe Blood Control I.V. Safety Catheter, and the MedSource ClearSafe Blood Control I.V. Safety Catheter

Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: August 15, 2023
Received: August 16, 2023

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 (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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223788

Device Name
The MedSource TrueSafe Blood Control I.V. Safety Catheter, and the MedSource ClearSafe Blood Control I.V. Safety Catheter

Indications for Use *(Describe)*
The MedSource TrueSafe Blood Control I.V. Safety Catheter, and the MedSource ClearSafe Blood Control I.V. Safety Catheter are indicated to sample blood or administer fluids intravenously. The MedSource TrueSafe Blood Control I.V. Safety Catheter and the MedSource ClearSafe Blood Control I.V. Safety Catheter may be used for any patient population with consideration given to adequacy for the vascular anatomy, appropriateness for the solution being administered and duration of the therapy.

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.

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K223788 – 510(k) Summary

Date of Prepared: September 15, 2023

A. Submitter:

MedSource International, LLC

8600 Shelby Court

Chanhassen, MN 55317

B. Contact Person:

Emilie Andrews, Regulatory and Quality Compliance Engineer

8600 Shelby Court

Chanhassen, MN 55317

Phone: 952-220-8875

C. Proposed Device:

Product Code: FOZ

Trade Name: The MedSource TrueSafe Blood Control I.V. Safety Catheter, and the MedSource ClearSafe Blood Control I.V. Safety Catheter

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

Classification Name: Intravascular catheter

Regulatory Reference: 21 CFR §880.5200

Review Panel: General Hospital

Classification: Class II

D. Predicate:

510(K): K161779

Product Code: FOZ

Trade Name: MedSource TrueSafe Safety IV Catheter and MedSource TrueSafe Comfort Safety IV Catheter

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

Classification Name: Intravascular catheter

Regulatory Reference: 21 CFR §880.5200

Review Panel: General Hospital

Classification: Class II

E. Indications for Use:

The MedSource TrueSafe Blood Control I.V. Safety Catheter, and the MedSource ClearSafe Blood Control I.V. Safety Catheter are indicated to sample blood or administer fluids intravenously. The MedSource TrueSafe Blood Control I.V. Safety Catheter and the MedSource ClearSafe Blood Control I.V. Safety Catheter may be used for any patient population with consideration given to adequacy for the vascular anatomy, appropriateness for the solution being administered and duration of the therapy.

F. Device Description:

The MedSource TrueSafe Blood Control I.V. Safety Catheter, and the MedSource ClearSafe Blood Control I.V. Safety Catheters are a safety medical device used for inserting a catheter into a patient's body for the delivery of fluids or drainage of fluids from a patient's body. This device is engineered to protect healthcare workers using it against accidental needle stick injury. In addition, this device also secures the needle (used to insert the catheter) within the catheter body with either a push button or slide safety mechanism, thus protecting healthcare and other personnel from accidental needle sticks.

The MedSource TrueSafe Blood Control I.V. Safety Catheter is comprised of a sharp needle attached to a needle hub with a catheter attached to a catheter hub. In the catheter hub there is a valve that, when activated, allows for the movement of fluids. In the 'inactivated' state prior to insertion of a male Luer, the movement of fluids is restricted. When the needle is retracted with the push button from the catheter the needle retracts into the body of the catheter and the needle is fully encapsulated.

The MedSource ClearSafe Blood Control I.V. Safety Catheter blood control mechanism is identical to the MedSource TrueSafe Blood Control I.V. Safety Catheter. The only difference in design features is the ClearSafe Blood Control has a slide safety mechanism that retracts the needle into the catheter body. The needle is also fully encapsulated to prevent accidental needlesticks. There is no difference in clinical use between the two models and the use of one over the other depends on user preference.

The MedSource TrueSafe and ClearSafe Blood Control Safety I.V. Catheter gauges are color coded for positive identification and range from 14G to 24G

Orange = 14G Grey = 16G Green = 18G Pink = 20G

Blue = 22G Yellow = 24G

G. SUMMARY OF COMPARISON TABLE OF PROPOSED DEVICE and PREDICATE

The proposed device is substantially equivalent to the predicate device the MedSource TrueSafe Safety I.V. Catheter (K161779). The MedSource IV Safety Catheter is also used as a reference device.

Comparison Point	Submission Device	Predicate Device	Discussion	Comments
	The MedSource TrueSafe Blood Control I.V. Safety Catheter, and the MedSource ClearSafe	The MedSource Truesafe Safety I.V. Catheter and the MedSource TrueSafe		

	Blood Control I.V. Safety Catheter	Comfort Safety I.V. Catheter (K161779)		
Indications for Use	The MedSource TrueSafe Safety IV Catheter and the MedSource TrueSafe Comfort Safety IV Catheter is indicated to sample blood or administer fluids intravenously. The MedSource TrueSafe Safety IV Catheter and the MedSource TrueSafe Comfort Safety IV Catheter may be used for any patient population with consideration given to adequacy for the vascular anatomy appropriateness for the solution being administered and duration of the therapy.	The MedSource TrueSafe Blood Control I.V. Safety Catheter, and the MedSource ClearSafe Blood Control I.V. Safety Catheter are indicated to sample blood or administer fluids intravenously. The MedSource TrueSafe Blood Control I.V. Safety Catheter and the MedSource ClearSafe Blood Control I.V. Safety Catheter may be used for any patient population with consideration given to adequacy for the vascular anatomy, appropriateness for the solution being administered and duration of the therapy	Same	
Principles of Operations	The needle is inserted to gain vascular access. Then blood will fill the flashback chamber. After the needle is placed it will be removed from	The needle is inserted to gain vascular access. Then blood will fill the flashback chamber. After the needle is placed it will be removed from	Same	

	the catheter leaving the catheter behind to allow for vascular access. As the needle is removed the needle is encapsulated inside the catheter body.	the catheter leaving the catheter behind to allow for vascular access. As the needle is removed the needle is encapsulated inside the catheter body.		
Catheter Outer Dimensions (O.D.) in mm	24G – 0.7 22G – 0.9 20G - 1.1 18G – 1.3 16G – 1.8 14G – 2.1	24G – 0.7 22G - 0.9 20G - 1.1 18G - 1.3 16G – 1.7 14G – 2.1	Same	
Catheter Effective Length in mm	Gauge Length 24G 19 22G 25 20G - TrueSafe 30 20G – ClearSafe 32 18G – TrueSafe 30 18G – ClearSafe 32 16G - TrueSafe 30 16G – ClearSafe 32 14G - TrueSafe 45	Gauge Length 24G 19 22G 25 20G 25 18G 25 16G 30 14G 45	Different	Clinical simulated use was conducted to validate the addition of the blood control valve did not change the effectiveness of the device. Performance testing was done to ISO 10555-5 and ISO 10555-1 to verify there was no change to the effectiveness of the device Based on the testing done the catheter effective length

				between the two IV Catheters does not affect the safety and effectivity of the device.
Number of Lumen(s)	Single Lumen	Single Lumen	Same	
Shape of Lumen(s)	Catheter hub – cylindrical with a taper down to the catheter	Catheter hub – cylindrical with a taper down to the catheter	Same	
Flow Rate for Each Lumen(s) in mL/min	Gauge Flow Rate 24G – TrueSafe 18 24G – ClearSafe 20 22G – TrueSafe 33 22G – ClearSafe 36 20G – TrueSafe 55 20G – ClearSafe 61 18G – TrueSafe 85 18G – ClearSafe 94 16G 200 14G 270	Gauge Flow Rate 24G 20 22G 36 20G 61 18G 92 16G 220 14G 297	Different	Flow rate variance between the two IV Catheters is within the allowance in ISO 10555-1 ANNEX -E This does not raise new or different questions of safety or effectiveness.
Proximal End configuration	Cupper	Cupper	Same	
Distal End configuration	Beveled	Beveled	Same	

Location of outlets or side ports	No ports	No ports	Same	
Diameter of outlets or side ports	Not applicable no ports present	Not applicable no ports present	Same	
Needle Stick Prevention Feature	Active – Manual safety mechanism Slide-ClearSafe and Push button-TrueSafe	Active – Manual safety mechanism Push button	Same Different	Clinical simulated use was conducted to validate the addition of the blood control valve did not change the effectiveness of the device. Performance testing was done to ISO 23908:2011 Based on the results of the testing this difference does not raise new or different questions of safety or effectiveness.
Sterilization	Terminal Ethylene Oxide (EtO gas)	Terminal Ethylene Oxide (EtO gas)	Same	
Catheter	Polyurethane (PUR) / (PTFE) Polytetrafluoroethylene	Polyurethane (PUR) / (PTFE) Polytetrafluoroethylene	Same	
Needle	Stainless Steal	Stainless Steel	Same	

Catheter Body	Polypropylene (PP)	K-Resin	Different	Clinical simulated use was conducted to validate the addition of the blood control valve did not change the effectiveness of the device. Performance testing was done to ISO 10555-5 ISO 10555-1, ISO 594-1 and ISO 594-2 to verify there was not change to the effectiveness of the device See the biocompatibility in Section H below for the list of biocompatibility testing done to verify there was no change in safety Based on the results of the testing this difference does not raise new or different questions of safety or effectiveness.
Catheter Holder	Polyacetal (POM)	Polyacetal (POM)	Same	
Needle Hub	K-Resin / MABS-T	K-Resin	Different	Clinical simulated use was conducted to validate the addition of the blood control valve did not change the effectiveness of the device.

				Performance testing was done to ISO 10555-5, ISO 10555-1, ISO 594-1, ISO 594-2 to verify there was not change to the effectiveness of the device See the biocompatibility in Section H below for the list of biocompatibility testing done to verify there was no change in safety Based on the results of the testing this difference does not raise new or different questions of safety or effectiveness.
Blood Control Valve	Polypropylene (PP) / Silicon / POM	Absent	Different	This valve is located inside the catheter hub. This is not present in the TrueSafe Safety IV models. This was added as an additional feature to help control possible blood flow out of the catheter hub Performance testing was done following ISO 594-1 and ISO 594-2 to verify there was not change

				to the effectiveness of the device Clinical simulated use was conducted to validate the addition of the blood control valve did not change the effectiveness of the device. See the biocompatibility in Section H below for the list of biocompatibility testing done to verify there was no change in safety Based on the results of the testing this difference does not raise new or different questions of safety or effectiveness.
Flashback Chamber	Polypropylene (PP) / Polycarbonate (PC)	ABS	Different	Performance and biocompatibility evaluation demonstrates that the addition of Polytetrafluoroethylene does not raise additional questions of safety and effectiveness. Clinical simulated use was conducted to validate the addition

				of the blood control valve did not change the effectiveness of the device. Performance testing was done to ISO 10555-5: and ISO 10555-1 to verify there was no change to the effectiveness of the device See the biocompatibility in Section H below for the list of biocompatibility testing done to verify there was no change in safety Based on the results of the testing this difference does not raise new or different questions of safety or effectiveness.
Hydrophobic Filter	Polyethylene (PE)	Poly-ethylene	Same	

H. Performance Data:

i. Performance Testing:

- ISO 10555-5: Intravascular catheters — Sterile and single-use catheters — Part 5: Over-needle peripheral catheters
- ISO 10555-1 Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements
- ISO 594-1Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment. — Part 1: General requirements
- ISO 594-2 Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings
- ISO 23908:2011 Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
- Simulated Clinical Use Study

ii. Biocompatibility

This device has prolonged contact with circulating blood.

- ISO 10993-5: 2009(E) Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10: 2010 (E) Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
- USP General Chapter <151> Pyrogen Test
- ISO 10993-11: 2017(E) Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
- ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials
- ISO 10993-4: 2017 (E) Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood
- ISO 10993-33:2015 Biological evaluation of medical devices — Part 33: Guidance on tests to evaluate genotoxicity — Supplement to ISO 10993-3
- ISO 10993-3:2014 Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity

- ISO 10993-6:2016(E) Biological evaluation of medical devices — Part 6: Tests for local effects after implantation
- ASTM F2888-19 Standard Practice for Platelet Leukocyte Count—An In-Vitro Measure for Hemocompatibility Assessment of Cardiovascular Materials
- ASTM F2382-18 Standard Test Method for Assessment of Circulating Blood-Contacting Medical Device Materials on Partial Thromboplastin Time (PTT)

iii. Sterility

- ISO 11135:2014 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
- ASTM D4332-22 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
- ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
- ASTM F88/F88M-21 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

I. Conclusion:

In summary, based on the indication for use, technological characteristics and performance testing, the differences between The MedSource TrueSafe Blood Control I.V. Safety Catheter, and the MedSource ClearSafe Blood Control I.V. Safety Catheter and the predicate did not raise new or different questions of safety and effectiveness.