August 7, 2020

MedSource Labs
Emilie Andrews
Quality Technician
8600 Shelby Court
Chanhassen, MN 55317

Re: K193278
Trade/Device Name: MedSource CathMED IV Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: July 13, 2020
Received: July 13, 2020

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,

for Payal Patel
Assistant Director, General Hospital
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193278

Device Name
MedSource CathMED IV Catheter

Indications for Use *(Describe)*
The MedSource CathMed IV Catheter is indicated to sample blood or administer fluids intravenously. The MedSource CathMED 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510 K-Summary- K193278

Date of Prepared: August 6, 2020

A. Submitter:
MedSource International, LLC
8600 Shelby Court
Chanhassen, MN 55317

B. Contact Person:
Emilie Andrews, Quality and Regulatory Affairs
8600 Shelby Court
Chanhassen, MN 55317
Phone: 952-472-0131

C. Proposed Device:
Product Code: FOZ
Trade Name: MedSource CathMED IV Catheter
Common Name: Intravascular catheter
Classification Name: Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days
Regulatory Reference: 21 CFR §880.5200
Review Panel: General Hospital
Classification: Class II

D. Predicate:
510(K): K131555
Product Code: FOZ
Trade Name: MedSource IV Safety Catheter
Common Name: Intravascular catheter
Classification Name: Catheter, Intravascular, Therapeutic, Short-Term Less Than 30Days
Regulatory Reference: 21 CFR §880.5200
Review Panel: General Hospital
Classification: Class II

E. Indications for Use:
The MedSource CathMED IV Catheter is indicated to sample blood or administer fluids intravenously. The MedSource CathMED 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.

F. Device Description:

The MedSource CathMED IV Catheter is indicated to sample blood or administer fluids intravenously. The MedSource CathMED 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.

Each MedSource CathMED IV Catheter is comprised of the following components: protective needle cover, color-coded catheter hub, radiopaque catheter tube, Teflon catheter holder, needle guide, medical grade stainless steel needle, needle hub, porous plug and gauge chamber. The MedSource CathMED IV Catheter components combine for an ergonomic design.

The device inserts a catheter intravenously by inserting a sharp needle with an over-the-needle catheter. Once the needle and catheter have been passed into a vein the catheter can be advance off the needle as the needle is removed while the catheter remains in the vein for short term use to sample blood or administer fluids.

The MedSource CathMED IV 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 Safety Catheter (K131555).

Comparison Point	**Submission Device** MedSource CathMED IV Catheter	**Predicate Device** MedSource IV Safety Catheter (K131555)	**Discussion**	**Comments**
Technology				
Indications for Use	The MedSource CathMED IV Catheter is indicated to sample blood or administer fluids intravenously. The MedSource 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	The MedSource IV Safety Catheter is indicated to sample blood or administer fluids intravenously. The MedSource IV Safety Catheter may be used for any patient population with consideration given to adequacy for the vascular anatomy appropriateness for the solution being	Same	

	duration of the therapy.	administered and duration of the therapy.		
Intended Use	The MedSource CathMED IV Catheter is indicated to sample blood or administer fluids intravenously. The MedSource CathMED 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 IV Safety Catheter is indicated to sample blood or administer fluids intravenously. The MedSource IV 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	
Distal End configuration	Beveled	Beveled	Same	
Proximal End configuration	Cupper	Cupper	Same	
Needle Stick Prevention Feature	Not present	Push-button needle shielding	Different	Absent in the submission device. A warning was added to the labeling of this product that a Needle Stick Prevention Feature is not present in this device. This does not affect the safety and effectiveness of the device.
Catheter Length **Catheter O.D.** **Needle Gauge**	Gauge Length mm OD mm 24G 19 0.7 22G 25 0.9	Gauge Length mm OD mm 24G 19 0.7 22G 25 0.9	Different	one new Gauge Length “20G length 33 mm OD 1.1 mm”

	20G 33 1.1 20G 25 1.1 18G 45 1.3 16G 45 1.8 14G 45 2.1	20G 25 1.1 18G 25 1.3 16G 30 1.7 14G 45 2.1		added to the submission device. This was added to expand the size availability for patient care. This does not affect the safety and effectiveness of the device.
Sterilization	Terminal Ethylene Oxide (EtO gas)	Terminal Ethylene Oxide (EtO gas)	Same	
Materials				
Catheter	Polyurethane (PUR) / (PTFE) Polytetrafluoroethylene	Polyurethane (PUR) / (PTFE) Polytetrafluoroethylene	Same	
Needle	Stainless Steel	Stainless Steel	Same	
Catheter Body	K-Resin	K-Resin	Same	
Catheter Holder	Polyacetal (POM)	Polyacetal (POM)	Same	
Needle Hub	K-Resin	K-Resin	Same	
Activation Lever	Absent	Polyacetal (POM)	Different	Absent in the submission device. A warning was added to the labeling of this product that a Needle Stick Prevention Feature is not present in this device. This does not affect the safety and effectiveness of

				the device.
Flashback Chamber	PUR/PTFE	PUR/PTFE	Same	
Hydrophobic Filter	Stainless Steel	Stainless Steel	Same	
Materials	K-Resin	K-Resin	Same	
Sterilization method	EtO	EtO	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

II. Biocompatibility

There were no changes to the material that impacted the biocompatibility of the device. A signed statement of conformance was included in place of testing as the testing from the predicate device was referenced.

- USP <788> Particulate Matter in Injections

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

I. Conclusion:

In summary, based on the indication for use, technological characteristics and performance testing, the differences between the MedSource CathMED IV Catheter and the predicate did not raise concern for safety and effectiveness. Therefore, we conclude that the subject device is substantially equivalent to the legally marketed predicate device.