DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 3, 2016

MedSource International, LLC
Ms. Laura Riggen
Quality & Regulatory Affairs Manager
401 Norex Drive
Chaska, Minnesota 55318

Re: K161779
Trade/Device Name: MedSource TrueSafe Safety IV Catheter and MedSource TrueSafe Comfort Safety IV Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: October 4, 2016
Received: October 6, 2016

Dear Ms. Laura Riggen:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161779

Device Name
MedSource TrueSafe Safety IV Catheter and MedSource TrueSafe Comfort Safety IV Catheter

Indications for Use *(Describe)*
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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary

K161779

Submitter: Medsource International, LLC
4201 Norex Drive
Chaska, MN 55318

Contact Person: Laura Riggen, Quality and Regulatory Affairs Manager
4201 Norex Drive
Chaska, MN 55318
Phone: 952-472-0131

Date Prepared: November 2, 2016

General Information:

Common Name: Catheter, intravascular, therapeutic, short-term
Regulatory Reference: 21 CFR §880.5200
Regulation Name: Intravascular Catheter
Product Code: FOZ
Classification: Class II
Panel: General Hospital
Proprietary Name: MedSource TrueSafe Safety IV Catheter and MedSource TrueSafe Comfort Safety IV Catheter
Predicate Device: MedSource IV Safety Catheter, K131555

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.

Description of the Device:

The MedSource TrueSafe Safety IV Catheter and the MedSource TrueSafe Comfort Safety IV Catheter are safety medical devices used for inserting a catheter into a patient's body for purpose of delivery of fluids or drainage of fluids from the patient.

The MedSource TrueSafe Safety IV Catheter and the MedSource TrueSafe Comfort Safety IV Catheter are comprised of the following components: protective needle cover, color-coded catheter hub, radiopaque catheter tube, catheter holder, needle guide, medical grade stainless steel needle, needle hub, porous plug and gauge chamber. The components combine for an ergonomic design that incorporate a safety feature that when the device is withdrawn, the needle is completely enclosed within the chamber protecting healthcare and other personnel from exposure to patient body fluids after the device has been discarded post-use. The retraction mechanism is activated by the push of a button.

The device is available in six gauges identified also by specific colors.

Part Number	Model Description	Color
MS-84414	TrueSafe Safety IV Catheter 14 Gauge x 1.75”	Orange
MS-84416	TrueSafe Safety IV Catheter 16 Gauge x 1.77”	Gray
MS-84418	TrueSafe Safety IV Catheter 18 Gauge x 1.88”	Green
MS-844182	TrueSafe Safety IV Catheter 18 Gauge x 1.16”	Green
MS-84420	TrueSafe Safety IV Catheter 20 Gauge x 1.88”	Pink
MS-844202	TrueSafe Safety IV Catheter 20 Gauge x 1.16”	Pink
MS-84422	TrueSafe Safety IV Catheter 22 Gauge x 1.00”	Blue
MS-84424	TrueSafe Safety IV Catheter 24 Gauge x 0.75”	Yellow
MS-84314	TrueSafe Comfort Safety IV Catheter 14 Gauge x 1.75”	Orange
MS-84316	TrueSafe Comfort Safety IV Catheter 16 Gauge x 1.77”	Gray
MS-84318	TrueSafe Comfort Safety IV Catheter 18 Gauge x 1.88”	Green
MS-843182	TrueSafe Comfort Safety IV Catheter 18 Gauge x 1.16”	Green
MS-84320	TrueSafe Comfort Safety IV Catheter 20 Gauge x 1.88”	Pink
MS-843202	TrueSafe Comfort Safety IV Catheter 20 Gauge x 1.16”	Pink
MS-84322	TrueSafe Comfort Safety IV Catheter 22 Gauge x 1.00”	Blue
MS-84324	TrueSafe Comfort Safety IV Catheter 24 Gauge x 0.75”	Yellow

Description of the Device Design:
The MedSource TrueSafe Safety IV Catheter and the MedSource TrueSafe Comfort IV Safety Catheter are substantially equivalent to the MedSource Safety Catheter (K131555).

	Submission Device ↓	**Predicate Device ↓**	**Comparison ↓**
Comparison Point ↓	MedSource TrueSafe Safety IV Catheter and MedSource TrueSafe Comfort Safety IV Catheter	MedSource IV Safety Catheter (K131555)	
Technology			
Mode of Operation	Aseptic technique, proper skin preparation and continued protection of the side are essential. Observe Universal Precautions on ALL patients.	Aseptic technique, proper skin preparation and continued protection of the side are essential. Observe Universal Precautions on ALL patients. A. Remove needle	Same

	A. Remove needle cover in a straight outward motion and inspect catheter unit. Rotate catheter 360°. B. Perform venipuncture. C. Observe blood return. Blood return will also be visible through the catheter. Lower and advance catheter unit 1/8". D. Holding the flash chamber stationary, advance the catheter off the needle into the vein. E. Before withdrawing needle from the catheter, depress button to retract the needle into the clear safety shield. Immediately discard unit in a puncture resistant, leak proof sharps container. If needle retraction does not occur, depress button again. Dispose of any unshielded needles immediately. Keep needlepoint away from body and fingers at all times. F. Connect tubing or adapter. G. Secure Catheter	cover in a straight outward motion and inspect catheter unit. Rotate catheter 360°. B. Perform venipuncture. C. Observe blood return. Blood return will also be visible through the catheter. Lower and advance catheter unit 1/8". D. Holding the flash chamber stationary, advance the catheter off the needle into the vein. E. Before withdrawing needle from the catheter, depress button to retract the needle into the clear safety shield. Immediately discard unit in a puncture resistant, leak proof sharps container. If needle retraction does not occur, depress button again. Dispose of any unshielded needles immediately. Keep needlepoint away from body and fingers at all times. F. Connect tubing or adapter. G. Secure Catheter	

Distal End configuration	Beveled	Beveled	Same
Proximal End configuration	Cupper	Cupper	Same
Needle Stick Prevention Feature	Push-button needle shielding	Push-button needle shielding	Same
Catheter Length Catheter O.D. Needle Gauge	Gauge Length mm OD mm 24G 19 0.7 22G 25 0.9 20G 25 1.1 18G 25 1.3 16G 30 1.7 14G 45 2.1	Gauge Length mm OD mm 24G 19 0.7 22G 25 0.9 20G 25 1.1 18G 25 1.3 16G 30 1.7 14G 45 2.1	Same
Sterilization Method	ETO	ETO	Same
Sterility Assurance Level (SAL)	10^{-6}	10^{-6}	Same
Shelf Life	5 Years	5 Years	Same
Materials			
Catheter	PUR/PTFE	PUR/PTFE	Same
Needle	Stainless Steal	Stainless Steal	Same
Catheter Body	K-Resin	K-Resin	Same
Catheter Holder	Polyacetal (POM)	Polyacetal (POM)	Same
Needle Hub	K-Resin	K-Resin	Same
Activation Lever	Polyacetal (POM)	Polyacetal (POM)	Same
Flashback Chamber	ABS	ABS	Same

Hydrophobic Filter	Poly-ethylene	Poly-ethylene	Same

Differences to Predicate Device

The MedSource TrueSafe Safety IV Catheter and the MedSource TrueSafe Comfort Safety IV Catheter has a notched-needle design to allow for instant blood flash while inserting the needle. This gives the caregiver an instant indication of vein penetration. A push off tab was added to the catheter hub to allow for a more careful insertion on the catheter. The Needle cover was modified for a better fit on the device to eliminate unintended activations. The differences do not raise new questions of safety and effectiveness as the differences enhance the products features. The instant blood flash and the push off tab enhance the care giver experience and allow for better insertion and vein penetration.

Nonclinical Tests

Nonclinical Bench Performance testing was performed to show that the MedSource TrueSafe Safety IV Catheter meets the standards set forth in ISO 10555-1: Sterile, single-use intravascular Catheter-General Requirements and ISO 10555-5: Sterile, single-use, intravascular Catheter-Over needle peripheral catheter.

Test Performed	**Criteria**	**Result**
Needle Point	Free from foreign parts with no blunt needles or dents	Pass
Flow Rate Through Catheter	Flow rate should be 55ml/min	Pass
Corrosion Resistance Test	There shall be no sign of corrosion	Pass
Method for Determining Tensile Force at Break	Minimum force at break shall be $\geq$ 5N	Pass
Catheter Collapse Through Aspiration Test	There shall be no ingress of air bubbles in to the syringe	Pass
Gauging Test	NO-GO side of the steel gauge should not be inside the luer.	Pass
Liquid Leakage From Conical Fitting Assembly Under Pressure	No liquid leakage should be there, when the assembly is subjected to withstand a pressure of 3.0 to 3.2 bar for 30sec.	Pass
Air Leakage from the Conical Fitting Assembly During	There should be no air bubble formation from the assembly up to 15sec.	Pass

<table>
<tr><td>Aspiration</td><td></td><td></td></tr>
<tr><td>Separation Force of Conical Fitting Assembly</td><td>There should be no detachment while applying a force of 10 newtons away from the fixture.</td><td>Pass</td></tr>
<tr><td>Stress Cracking</td><td>There should not be any sign if cracking in the device luer fitting</td><td>Pass</td></tr>
<tr><td>Unscrewing Torque of Fitting Assembly</td><td>There shall be no separation when the fitting is tested</td><td>Pass</td></tr>
<tr><td>Ease of Assembly</td><td>Male reference fitting should insert without any jerk and fit together securely.</td><td>Pass</td></tr>
<tr><td>Resistance to Overriding</td><td>There shall not be any unusual damage on either of the female part or to the reference fitting.</td><td>Pass</td></tr>
<tr><td>Radiopacity of Catheter</td><td>Visually compare the images of the test specimen to the background on the film.</td><td>Pass</td></tr>
<tr><td>Catheter Elongation Testing</td><td>Measure the gauge length and tensile strength at break</td><td>Pass</td></tr>
<tr><td>Catheter Stiffness Testing</td><td>As per manufacturer data, Shore: D-60 ± 4</td><td>Pass</td></tr>
<tr><td>Resistance to Disinfection</td><td>No visual damage shall be present. As per ISO 527, the catheter shall show no degradation in tensile properties. Catheter tube elongation should be greater than 100% (as in control i.e., non-exposed samples)</td><td>Pass</td></tr>
<tr><td>Needle Hub Detachment Force</td><td>20N when testing needles of nominal O.D ≥ 0.6 mm</td><td>Pass</td></tr>
<tr><td>Needle Safety Mechanism Activation Test</td><td>Check whether the activation Lever activated smoothly without any jerk and check the complete length of the needle enclose to the safety chamber.</td><td>Pass</td></tr>
<tr><td>Venipuncture Process: Needle Stick</td><td><table><tr><th>GAUGE</th><th>MAX PENETRATION LOAD (Newton)</th><th>MAX FRICTION (Newton)</th></tr><tr><td>14</td><td>2.70N</td><td>0.70N</td></tr><tr><td>16</td><td>2.50N</td><td>0.60N</td></tr><tr><td>17</td><td>2.40N</td><td>0.60N</td></tr><tr><td>18</td><td>1.90N</td><td>0.50N</td></tr><tr><td>20</td><td>1.60N</td><td>0.40N</td></tr><tr><td>22</td><td>1.50N</td><td>0.35N</td></tr><tr><td>24</td><td>1.35N</td><td>0.34N</td></tr><tr><td>26</td><td>1.30N</td><td>0.45N</td></tr></table></td><td>Pass</td></tr>
<tr><td>Venipuncture Process: Tightness Between Catheter Tube</td><td>The distance should not exceed maximum value of 1.0mm and should be greater than 0.1mm.</td><td>Pass</td></tr>
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and Cannula		
Activation Testing	That 97.5% of the time the failure rate would be no higher than 0.7% and 99.5% confident that the failure rate is not higher than 1.1%.	Pass
Biocompatibility	Sensitization Testing (Primary Skin Irritation) Standard ISO 10993 Part 10	Pass
Biocompatibility	Intracutaneous Reactivity Test Standard 10993 Part 5	Pass
Biocompatibility	In-Vitro Cytotoxicity Standard ISO 10003 Part 5	Pass
Biocompatibility	Systemic Toxicity Standard ISO 10993 Part 11	Pass
Biocompatibility	Hemocompatibility Test Standard ISO 10993-1	Pass

Simulated Clinical Use Testing

500 units were tested, 0 units failed to activate the safety feature. Based on that, it can be determined that 97.5% of the time the failure rate would be no higher than 0.7% and 99.5% confident that the failure rate is not higher than 1.1%

Conclusion:

As shown by data in the table above, there are no significant performance specification differences between the MedSource TrueSafe Safety IV Catheter and the MedSource TrueSafe Comfort Safety IV Catheter and the substantially equivalent device. Therefore, we conclude that the devices are substantially equivalent.