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

July 15, 2015

MedSource International
Ms. Laura Riggen
Director, Quality and Regulatory Affairs
4201 Norex Drive
Chaska, Minnesota 55318

Re: K150611
Trade/Device Name: MedSource ClearSafe Safety IV Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular catheter
Regulatory Class: II
Product Code: FOZ
Dated: June 5, 2015
Received: June 8, 2015

Dear Ms. 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" (21CFR 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 yours,

for Erin I. Keith, M.S.
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)*
K150611

Device Name
MedSource ClearSafe Safety IV Catheter

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

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

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: Tuesday, July 14, 2015

General Information:

Regulatory Reference: 21 CFR §880.5200
Classification Name: Intravascular Catheter
Product Code: FOZ
Common Name: Catheter, intravascular, therapeutic, short-term
Classification: Class II
Panel: General Hospital
Proprietary Name: MedSource ClearSafe Safety IV Catheter
Single Use: Yes
Sterile: Yes
Predicate Device: K131555 MedSource IV Safety Catheter

Indication for Use:

The MedSource ClearSafe Safety IV Catheter is indicated to sample blood or administer fluids intravenously. The MedSource ClearSafe 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 ClearSafe Safety IV Catheter is a medical device used for inserting a catheter into a patient's body for purpose of delivery of fluids or drainage of fluids from the patient's body. The device is equipped with a safety feature intended to prevent needle stick injuries. This device is engineered to protect healthcare workers using it against accidental needle stick injury and exposure to parts of the device that have come in contact with patient's blood or other body fluids, and have hence been potentially contaminated with infectious agents. In addition this device also secures the needle (used to insert the catheter) in an enclosed chamber, thus protecting healthcare and other personnel from exposure to patient body fluids after the device has been discarded post-use.

The MedSource ClearSafe Safety IV Catheter is 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. The retraction mechanism is activated by the user using only one hand by means of a sliding motion.

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

Part Number	Model Description	Color
MS-84114	MedSource ClearSafe Safety IV Catheter 14 Gauge	Orange
MS-84116	MedSource ClearSafe Safety IV Catheter 16 Gauge	Gray
MS-84118	MedSource ClearSafe Safety IV Catheter 18 Gauge	Green
MS-841182	MedSource ClearSafe Safety IV Catheter 18 Gauge	Green
MS-84120	MedSource ClearSafe Safety IV Catheter 20 Gauge	Pink
MS-841202	MedSource ClearSafe Safety IV Catheter 20 Gauge	Pink
MS-84122	MedSource ClearSafe Safety IV Catheter 22 Gauge	Blue
MS-84124	MedSource ClearSafe Safety IV Catheter 24 Gauge	Yellow

Predicate Device Comparison:
The MedSource ClearSafe Safety IV Catheter is substantially equivalent the MedSource Safety Catheter (K131555).

Section 1 Comparison of Technological Characteristics:

	Submission Device ↓	**Predicate Device ↓**	**Comparison ↓**
Comparison Point ↓	MedSource ClearSafe Safety IV Catheter (K150611)	MedSource IV Safety Catheter (K131555)	
Technology			
Distal End configuration	Beveled	Beveled	Same
Proximal End configuration	Cupper	Cupper	Same

Intended Use	The MedSource ClearSafe Safety IV Catheter is indicated to sample blood or administer fluids intravenously. The MedSource ClearSafe 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 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
Needle Stick Prevention Feature	Sliding activation needle Shielding	Push-button needle shielding	The safety feature activation is different but acts in the same fashion.
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 32 1.3 16G 32 1.7 14G 32 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
Materials			
Catheter	PUR/PTFE	PUR/PTFE	Same
Needle	Stainless Steel	Stainless Steel	Same
Catheter Body	K-Resin	K-Resin	Same
Catheter Holder	Polyacetal (POM)	Polyacetal (POM)	Same
Needle Hub	ABS	ABS	Same
Activation Lever	NA	Polyacetal (POM)	There is no Activation lever on

			the Submission Device.
Flashback Chamber	ABS	ABS	Same
Hydrophobic Filter	Poly-ethylene	Poly-ethylene	Same

Section 2 Comparison of Non-Clinical Data:

Non Clinical Tests:

The following tests were performed to show that the MedSource ClearSafe 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.

Needle Point Geometry (Bevel)
Tested per ISO 10555-5:1996(E)
Conclusion:
Based on the test conditions contained in the Standard, the cannula is subsequently complying with the requirements of ISO 10555-1.

Gravity Flow
Determination of flow rate through catheter (using water 1, 000kg/$m^{3,}$ measure the efflux not less than 30s, express the average flow rate
Tested per ISO10555-5:1996(E) Annex B
Conclusion:
As per the test conditions contain herein, the flow rate observed from the catheter is under the specified limit 55 ml/min.

Corrosion Resistance Test
Tested per ISO10555-1:1995
Conclusion:
As per the test conditions contain herein, the cannula/needles are checked visually for signs of corrosion and the results are complies the condition as per EN ISO 10555-1.

Method for Determining Force at Break
(Hub-tube tensile test, strain rate: 20mm/min/mm. test speed: 400mm/min-min force at break 5N OD 0.75-1.15)
Tested Per ISO10555-1:1995 Annex B.
Conclusion:
As per the test conditions contain herein, the observed value at break is under the specified limit. i.e. Average force at break – 22N.

Catheter Collapse
Air leakage during aspiration.(Visual inspection made for ingress of air bubbles to the syringe)
Tested per ISO10555-1 Annex D
Conclusion:
As per the test conditions contain herein, the whole assembly is checked for ingress of air bubbles and there was no air bubble formation observed from the hub assembly up to 30sec.

Gauging Test
Tested per ISO594/1-1986(E) Sec. 5.1
Conclusion:
As per the test conditions contain herein, the catheter luer (body) is complies with the requirement of EN 20594-1 as per the steel gauge.

Liquid Leakage from the Conical Fitting Assembly under Pressure
Tested per ISO594/1-1986(E) Sec. 5.2
Conclusion:
As per the test conditions contain herein, there is no liquid leakage observed from the assembly at 3bar up to 15min.

Air Leakage from the Conical Fitting Assembly during Aspiration
Tested per EN 20594-1, ISO 10555-1 Annex D
Conclusion:
As per the test conditions contain herein, the whole assembly is checked for ingress of air bubbles and there was no air bubble formation observed from the hub assembly up to 30sec.

Liquid Leakage under Pressure
(300 to 320 kPa to be generated or 30s)
Tested per EN 20594-1 Sec. 5.2, ISO 10555-5:1995(E) Annex C
Conclusion:

As per the test conditions contain herein, there is no liquid observed from the assembly at 3bar up to 15min.

Separation Force of Conical Fitting Assembly
Tested per ISO594-1 Sec. 5.4
Conclusion:
As per the test conditions contain herein, the average force 7.4N is observed for the separation of connection, which is under the specified limit.

Stress Cracking
Tested per ISO594-1 Sec. 5.5, ISO594-2:1998(E) Sec. 5.8
Conclusion:
As per the test conditions contain herein, there is no sign of any stress or cracking on the device material as well as no leakage was observed from the conical fitting up to 1min.

Unscrewing Torgue of Fitting Assembly
Tested per ISO594-2:1998(E)
Conclusion:
As per the test conditions contain herein, the average force 0.06 Nm is observed to unscrew the male luer assembly from the female luer assembly.

Ease of Assembly
Tested Per ISO594-2:1998(E) Sec. 5.6
Conclusion:
As per the test conditions contain herein, the male reference fitting inserts without any jerk and fits securely.

Resistance to Overriding
Tested Per ISO594-2:1998 (E) Sec. 5.7
Conclusion:
As per the test conditions contain herein, there are no damage observed during the fitting of male reference fitting to the female luer.

Radiopacity of Catheter
Tested per ASTM F640-07
Test Result:
Passed
X- Ray image is as attached.

Catheter Elongation Testing
(Determination of Elastic Modulus)
Tested per ISO 527-1

Acceptance Criteria:
The strength at break should be 25 N for the tube with outer diameter > 1.
Conclusion:
Passed

Catheter Flexural Fatigue
Strength Tolerance
Tested per BS EN 13868:2002
Conclusion:
As per the test conditions contain herein, average kink length observed is as above and there is no kink mark observed while the flow rate is observed <50% from the straight tube.

Catheter Stiffness
(Durometer)
Tested per ASTM D2240-05:2010 (R)
Conclusion:
As per the test conditions contain herein, the value observed is complies the hardness property of the material.

Resistance to Disinfection
(1-Alcohol 70%, 2- Mixture of Povidone Iodine 10%, 3-Chlorhexidine Gluconate 0.5%)
Conclusion:
As per the test conditions contain herein, there is no damage observed during the visual inspection of the catheter.

Activation Testing:

Activation Testing was completed on the MedSource ClearSafe Safety IV Catheter. 500 Units of the MedSource ClearSafe Safety IV Catheter were obtained. Each unit was opened and the safety feature was activated and observed, making note of any deviation and the success or failure of the anti-needle stick feature. Failure is defined as a needle stick injury or a significant problem with the safety feature that may lead to an injury.

Testing was completed on April 7, 2014 in 5 Test Cycles of 100.

Conclusion of Activation Testing:

Out of the 500 MedSource ClearSafe Safety IV Catheters that were tested, 0 units failed to activate the safety feature. Based on that, it can be determined there is no issue outside of the confidence interval as stated in the Clinical Simulation 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%)

Simulation Testing:
Clinical Simulation Testing was completed over the course of April 1st –April 9th, 2015 for the MedSource ClearSafe Safety IV Catheter. The test was conducted using a variety of Health Care Professionals.

Each participant was able to use the MedSource ClearSafe Safety IV Catheter with little instruction and had no issues being able to activate the safety feature.

Conclusion of Simulation Testing:
Based on the results of the Safety Feature Evaluation form it can be determined that the Medsource ClearSafe Safety IV Catheter's safety feature:

1. Is no more difficult to use then other similar devices
2. Is easy to activate and does not require extensive training
3. Does not interfere with normal use of the product.
4. Is required to be used when correctly operating the device
5. Eliminates the need for exposed needles in connections
6. Works well with a variety of hand sizes and under various, common uses (gloved, wet, dry hands)
7. Operates reliably- 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%
8. Exposed sharp is covered after use and prior to disposal.

Conformity to the Following Recognized Standards:

1. ISO 10555-5: Sterile, single use intravascular catheters
2. ISO 11607-1/2 Packaging for terminally sterilized medical devices
3. BS EN 868-5 Packaging materials and systems for medical devices which are to be sterilized. Heat and self-sealable pouches and reels of paper and plastic film construction-Requirements and test methods
4. DIN 58953-6 "Sterilization paper for bags and tubing pickings ''.Testing for germ proof ness in moisture with passage of air
5. ASTM F 2054 Standard test method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization within Restraining Plates.
6. ASTM F 1980-02 Standard Guide for Accelerated Aging of Sterile Medical Device Packages
7. ASTM D638 Plastic Tensile Testing

8. ISO 10993: Part 10 Biological evaluation of medical devices: Test of irritation and skin sensitization.

Conclusion:

As shown by data in the table above, there are no significant performance specification differences between the MedSource ClearSafe Safety IV Catheter and the predicate device. Testing was done to confirm the adequate performance of the device and safety feature. Therefore, we conclude that the performance specifications demonstrate that the subject device is substantially equivalent to the legally marketed predicate device.