



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

May 8, 2015

MedSource International, LLC
c/o Mr. Howard Cooper
Principal Consultant
EQACT INC.
11715 Fox Road
Indianapolis, IN 46236

Re: K150333

Trade/Device Name: MedSource Sharps Dart
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: II
Product Code: MMK
Dated: March 10, 2015
Received: March 12, 2015

Dear Mr. Cooper:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH 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

Indications for Use

510(k) Number (if known)

K150333

Device Name

MedSource Sharps Dart

Indications for Use (Describe)

The MedSource Sharps Dart is a non-sterile single-use disposable sharps container with a permanent closure system for a contaminated 1 ml or smaller syringe. Its intended use is by health care professionals in a setting where standard sharps containers are not accessible such as EMS, home healthcare, and laboratories. Its permanent closure system protects the user prior to disposal by incineration or decontamination by autoclave.

MedSource Sharps Dart Model No. MS-64250

Color-Clear/translucent with red closure

Length-17cm (6.7 in.)

Diameter-3cm (1.2 in.)

Empty Weight- 255 gm (0.9 oz)

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.

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
PRASStaff@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."



Toll Free: 800-876-8264
 Phone: 952-472-0131
 Fax: 952-472-0136
 www.gomedsource.com

Medical Supplies for the Healthcare Professional

4201 Norex Drive Chaska, MN 55318 USA

510 (k) Summary

SECTION 5

Date Prepared: May 8, 2015

1. General Information

Submission Sponsor		Submission Correspondent	
MedSource International 4201 Norex Drive Chaska, MN 55318		Howard T. Cooper EQACT, INC. 11715 Fox Rd. Suite 400 Indianapolis, IN 46236 317-826-4398 office	
Device Identification		Predicate identification	
Characteristic	Submission Device	Predicate A	Predicate B
Trade name	MedSource Sharps Dart	Covidien Sharps Shuttle /Sharps Shuttle with Locking Mechanism*	B Travel Savvy Sharps Container
510(K)	K150333	K972279	K140285
Regulatory Name	Hypodermic Single-Lumen Needle	Hypodermic Single-Lumen Needle	Hypodermic Single-Lumen Needle
Common name	Sharps Container	Sharps Container	Sharps Container
Product Code	MMK	FMI	MMK
Classification	Class II	Class II	Class II
CFR reference	880.5570	880.5570	880.8570
Classification Panel	General Hospital	General Hospital	General Hospital
Catalog No.	MS-64250	Model 8801	BTS-702
<ul style="list-style-type: none"> *Covidien Sharps Shuttle, formerly Kendall P2 Shuttle Sharps Container manufactured by Sage Products 			

2. Device Description

The MedSource Sharps Dart (MSD) sharps container consists of two injected molded parts-a tubular tapered cone and a polypropylene closure. Its small size of 0.6 L qualifies it as a pocket sharps container as defined by ISO 23907 First Edition 2012-09-01, Sharps injury protection-Requirements and test

methods-Sharps containers. It is designed for the storage, such sharps as small syringes, blood needles, lancets, and angio-caths prior to disposal consideration. It's intended to be used in remote settings for sharps containers are not convenient and accessible such as EMS, home healthcare, etc. It is a single use device.

The MSD sharps container was designed using the above standard, ISO 23907, and its design includes the required features specified in the standard. It meets the performance requirements for the standard. In addition, it has also been tested by an independent laboratory to meet the requirements for puncture resistance specified in ASTM F2132-01 (Re-approved in 2008). Both standards are FDA recognized.

The predicate device, Covidien Sharps Shuttle, was selected because of its tubular-conical configuration with a polypropylene hinge-closure , which is very similar to the construction of the MedSource Sharps Dart. They are also similar in their weight and dimensions. When comparing such factors as Indications for Use, Performance, Technology, and method of manufacture, the data shows substantial equivalence between both the Covidein Sharps Shuttle and the MedSource Sharps Dart.

Although both devices are considered to be substantially equivalent, they have been or are being cleared at different periods of regulation. At the time that the predicate device was approved, there was not an FDA recognized standard for sharps container. However, Medsource Sharps Dart was designed following FDA recognized standards for the products with respect to puncture resistance testing and leak testing.

3. Standards

The following FDA recognized standards were used in the preparation of this 510K:

Standard	Summary of Compliance to Standard
ISO 23907 First edition 2012-09-01-Sharps injury protection— Requirements and test methods— Sharps containers	Medsource Sharps Dart compliance to the definition of the pocket sharps container. <ol style="list-style-type: none"> 1. Summary report prepared demonstrating compliance to the standard for pocket sharps container 2. Testing was conducted for puncture resistance and leak resistance and product met the testing criteria
ASTM F2132- 01 (2008) Standard Specification for Puncture Resistance of Materials Used in Containers for Discarded Medical Needles and Other Sharps	See revised standards Summary report prepared demonstrating compliance to standard. See Section 18, Performance Testing

FDA OSHA	29 CFR 1910.1030	Meets requirements by compliance to applicable parts of ISO 23907 (Impact Test) and ASTM F 2132 (Puncture Resistance)
----------	------------------	---

4. Device Comparison

Predicate ID	Submission Device	Predicate A	Predicate B
Trade Name	MedSource Sharps Dart K150333	Covidien Sharps Shuttle With Locking K972279	B Travel Savvy Sharps Container K140285
Indications for Use	<p>The MedSource Sharps Dart is a non-sterile single-use disposable sharps container with a permanent closure system for a contaminated 1ml or smaller syringe. Its intended use is by health care professionals in a setting where standard sharps containers are not accessible such as EMS, home healthcare and laboratories. Its permanent closure system protects the user prior to disposal by incineration or decontamination by autoclave.</p> <p>MedSource Sharps Dart Model No. MS-64250</p> <p>Color-Clear/translucent with red closure</p>	<p>The Sharps Shuttle and Sharp Shuttle with Locking Mechanism are single use, non-sterile, disposable, sharps transport containers intended for use in any setting where standard sharps containers are not conveniently accessible, such as EMS home health care, etc</p>	<p>The Travel Savvy Sharps Container is a single-use device intended for disposal of sharps waste by a single user in a private site of use. When mounted with the appropriate bracket, the Travel Savvy Sharps Container can be used for sharps disposal in vehicles. The B Travel Savvy Sharps container color is red. The length of the device is 6.5 inches, the width is 2.1 inches and the height is 2.3 inches. The aperture opening is 1.5 inches wide and the length is 2.5 inches.</p>

	Length-17cm (6.7 in.) Diameter-3cm (1.2 in.) Empty Weight- 255 gm (0.9 oz)		
RX or OTC	OTC	OTC	OTC
Material	Polypropylene	Polypropylene	Polypropylene
Sharps Access	Top opening	Top Opening	Top Opening
Sharps Closure	Hinged closure	Hinged closure	Hinged closure
Dimensions & Weight	Length-17cm (6.7 in.) Diameter-3cm (1.2 in.) Empty Weight- 255 gm (0.9 oz)	Approximately 6in. long & 1 in. diameter Empty weight not available	The length of the device is 6.5 inches, the width is 2.1 inches and the height is 2.3 inches. The aperture opening is 1.5 inches wide and the length is 2.5 inches.
Single use	Yes	Yes	Yes
Non-sterile	Yes	Yes	Yes
Translucent	Yes	Yes	Yes
Impact and leak resistance	Yes	Yes	Yes
Needle Penetration Resistance-	Yes	Yes	Yes

5. Comparison Results

Category of comparison	Results
1. Regulatory Requirements Characteristics	Equivalent
2. Indications for Use & RX/OTC	Equivalent
3. Design & Construction and Method of Manufacture	Equivalent
4. Technology	Equivalent
5. Product Features	Equivalent

6. Test Methods

Test Methods	Standards
Puncture Resistance	ISO 23907- Section 4.2.4
Resistance to Leakage	ISO 23907- Section 4.2.5
Puncture Resistance	ASTM- F2132-01

7. Conclusion

The MedSource Sharps Dart sharps container was compared to the above predicate devices in such areas as technology, indications for use, materials of construction, performance testing, product testing, and product features. Based on the review of this data, the data supports the conclusion that the subject device is substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised by the introduction this device. Therefore, we conclude that the subject device is as safe, as effective, and performs as well as the legally marketed predicate devices [Covidien Sharps Shuttle/ Sharps Shuttle with Locking Mechanism (K972279) and B Travel Savvy Sharps Container (K140285)].