FEB 2 4 2012

510(k) Summary

Submitter's References
Shantou Wealy Medical Instrument Co., Ltd. North Jinhuan Road (Near of Qishan Mid-School) Shantou City, Guangdong Province, China Zip: 515064 FDA Registration Number: 3005202235 Owner/Operator Number: 9074040 Tel:+86-754-88218123 Fax:+86-754-82121654
Official Correspondent
IRC- Mr. Charles Mack 77325 Joyce Way Echo, Oregon 97826 Ph. 931-625-4938 Fax: 541-376-5063 Email: charliemack@irc-us.com
Summary Contents
• Submitted Device • Device Description • Statement of Intended Use • Substantial Equivalence • Safety • Effectiveness • Conclusions

1. Submitted Device

Trade Name	Automatically Retractable Safety Syringe(with fixed needle) 5cc/ml 22×11/4
Common Name	Syringe, anti-stick
Classification Name	Piston Syringe

1.1. Predicate/Legally Marketed Device

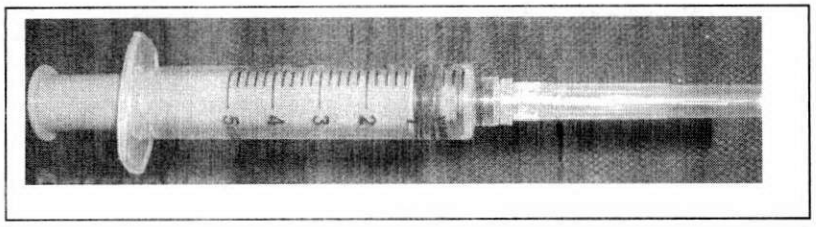
Model	Manufacturer	K Number	Submitted Device
Anti-Stick Syringe With Integral Hypodermic Needle Vanishpoint Syringe	Retractable Technologies, Inc.	K970803	Automatically Retractable Safety Syringe(with fixed needle) 5cc/ml 22×11/4

1.2. Proposed Indications

The proposed indications for the predicate Anti-stick Vanishpoint and the submitted Automatically Retractable Syringe are the same. The design, intended use and construction are exactly the same.

Both the predicate and the submitted device are single-use, anti-stick piston type syringes. The function of the predicate and the submitted device is to provide a safe and reliable method of injecting medication into a patient. Both devices work like a simple piston syringe except for the syringe's ability to retract the contaminated needle inside of the syringe immediately after patient injection. Needle retraction is activated by the syringe user.

2. Device Description

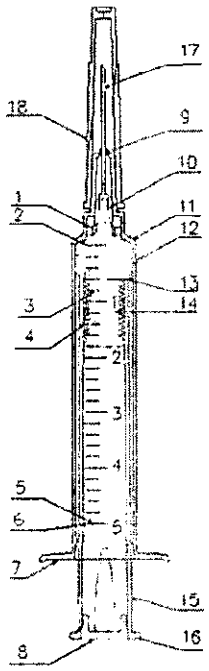


2.1 Description :

The Automatically Retractable Safety Syringe (with fixed needle) 5cc/ml 22×11/4 is a piston syringe. The device is intended for medical purposes and consists of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle. The device is used to inject fluids into the body.

Automatically Retractable Safety Syringe (with fixed needle) (5cc/ml 22×11/4") works like a conventional hypodermic syringe except for its ability to retract the contaminated needle inside of the syringe immediately after patient injection. Needle retraction is activated by the syringe user. The needle retracting mechanism is activated by a spring action mechanism after injection is completed, while the exposed needle remains safety inside the empty syringe barrel for disposal.

2.2 Structure



No.	Name.
1	Leak-proof ring
2	Zero line
3	Capacity graduation
4	spring
5	Nominal capacity graduation
6	capacity line of overall graduation
7	Finger grips of barrel
8	Top cap
9	Conical tip
10	Needle file
11	Barrel
12	Piston
13	Warning line
14	Retraction device
15	Push cylinder
16	Push button
17	Needle
18	Needle covers

The plunger rod, barrel, needle hub, needle protector and slider are made from polypropylene. The spring and cannula are made from Stainless steel. The piston is made from isoprene rubber and the piston O-ring is made from silicon dioxide. The components are glued together with acrylic glue. All of these components have been tested to verify biocompatibility.

3. Statement of Intended Use

Automatically Retractable Safety Syringe (with fixed needle) (5cc/ml 22×1-1/4) is a sterile, single-use, disposable and non-reusable, retractable safety syringe which is intended to provide a safe and reliable method for intramuscular and subcutaneous injection of medication into a patient.

4. Substantial Equivalence

The submitted Automatically Retractable Safety Syringe is constructed to perform like the predicate Vanishpoint Syringe. Both devices are simple piston syringes with ability to retract the used needle into the body after use. Both devices are single use devices and constructed in the same manner. The submitted device and predicate have undergone similar safety and performance testing and the submitted device has passed these tests.

5. Differences

Please refer to the tables on the following pages for noted differences.

Element of comparison	Subject Device	Claimed SE Device
Company	Shantou Wealy Medical Instrument Co.,Ltd.	Retractable Technologies, Inc.
FDA510(K) Number	N/A	K970803
Device Name	Automatically Retractable Safety Syringe with Fixed Needle	VanishPoint™ Syringe
Volume	5ml	5 ml and 10ml
Needle length	1-1/4 Inch	1-1/2 Inch
Available needle gauge sizes	22G	20/21/22/25G
Intended Use	Automatically Retractable Safety Syringe (with fixed needle) (5ml/CC 22G×1 1/4") is a sterile, single-use, disposable and non-reusable, retractable safety syringe which is intended to provide a safe and reliable method for intramuscular and subcutaneous injection of medication into a patient.	The function of the VanishPoint™ Syringe is to provide a safe and reliable method of injecting medication into a patient or withdrawing blood from a patient. The VanishPoint™ Syringe works like a conventional hypodermic syringe except for its ability to retract the contaminated needle inside of the syringe immediately after patient injection. Needle retraction is activated by the syringe user. Because the contaminated needle is automatically withdrawn into the syringe barrel, The syringe user is protected from accidental needle sticks. These accidental needle sticks would occur between removing the needle from the patient and disposing of the syringe in a sharps disposable container.
Principle of operation	The needle is automatically retracted from the patient into the barrel of the syringe when the plunger is fully depressed. Automatically Retractable Safety Syringe reduces the risk of healthcare worker exposure to hazardous drugs during reconstitution, preparation, transport, and disposal.	The needle is automatically retracted from the patient into the barrel of the syringe when the plunger is fully depressed. VanishPoint™ Syringe reduces the risk of healthcare worker exposure to hazardous drugs during reconstitution, preparation, transport, and disposal.
Syringe type	Plunger, anti-stick with hypodermic needle	Plunger, anti-stick with hypodermic needle
Sites of use	Hospitals, clinics, laboratories	Hospitals, clinics, laboratories
Safety Features	Active safety feature, manually activated by users	Active safety feature, manually activated by users

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Element of comparison	Subject Device	Claimed SE Device
Specific drug use	Conventional drugs	Conventional drugs
Needle tip configuration	Tri-Beveled Tip	Tri-Beveled Tip
Nozzle type	Needle and hub are integral to the syringe, not separable.	Needle and hub are integral to the syringe, not separable.
Barrel marking specs	Scale :conforms to ISO 7886-1:1993/ Corrigendum 1:1995	Scale :conforms to ISO 7886-1:1993/ Corrigendum 1:1995
Gradations legibility	0.2ml	0.2ml
Needle cover color	colorless	colorless
Lubricant composition	Polydimethylsiloxane (PDMS)	Polydimethylsiloxane (PDMS)
Lubricant amount/ cm^2	<0.25mg/cm^2	<0.25mg/cm^2
Barrel transparency	Clear	Clear
Delivery accuracy	conforms to ISO 7886-1:1993/ Corrigendum 1:1995	conforms to ISO 7886-1:1993/ Corrigendum 1:1995
Needle cover strength	<15N	<15N
Hub/needle bond strength	40N	40N
Biocompatibility	Conform to ISO 10993-1	Conform to ISO 10993-1

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Element of comparison	Subject Device	Claimed SE Device
Materials	Plastic parts : Polypropylene Piston : Isoprene rubber O-ring: Silicon dioxide Needle : Stainless steel	Plastic parts : Polypropylene Piston : Isoprene rubber O-ring: Silicon dioxide Needle : Stainless steel
Syringe type	Antistick syringe	Antistick syringe
Reuse	Non-reusable	Non-reusable
Sterilization	EO Sterilization	Gamma Sterilization

END

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Shantou Wealy Medical Instrument Company, Limited
C/O Mr. Charlie Mack
Principal Engineer
IRC
77325 Joyce Way
Echo, Oregon 97826

FEB 2 4 2012

Re: K113587
Trade/Device Name: Automatically Retractable Safety Syringe (with Fixed Needle) 5ml/CC 22G^{x}1 1/4"
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: November 27, 2011
Received: December 7, 2011

Dear Mr. Mack:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113587

Indications for Use

510(k) Number (if known):

Device Name: Automatically Retractable Safety Syringe (with Fixed Needle) 5ml/CC 22G×1 1/4"

Indications For Use:

Automatically Retractable Safety Syringe (with fixed needle) (5cc/ml 22×1-1/4) is a sterile, single-use, disposable and non-reusable, retractable safety syringe which is intended to provide a safe and reliable method for intramuscular and subcutaneous injection of medication into a patient.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for RZC feb 22, 2012
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113587