Shantou Wealy Medical Instrument CO.,Ltd.
℅ Eva Li
Consultant
Shanghai SUNGO Management Consulting Co. Ltd.
Room 1401, Dongfang Building, 1500# Century Ave.,
Shanghai, 200122
China

Re: K222452
Trade/Device Name: Disposable Automatically Retractable Safety Syringes (with detachable needle)
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: MEG, FMF, FMI
Dated: October 24, 2022
Received: October 24, 2022

Dear Eva Li:

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,

Courtney Evans -S

Digitally signed by Courtney Evans -S
Date: 2022.11.23 06:45:27 -05'00'

For CAPT Alan Stevens
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222452

Device Name

Disposable Automatically Retractable Safety Syringes (with detachable needle)

Indications for Use *(Describe)*

The Automatically Retractable Safety Syringes with detachable needle devices are indicated for use where a safe and reliable method for intramuscular and subcutaneous injection of medication in a patient is desired.

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
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 – K222452

1. Submitter Information

Name: Shantou Wealy Medical Instrument CO.,Ltd.
Address: North Jinhuan Road(near of Qishan mid-school), Shantou, 515064, Guangdong, China

2. Correspondent Information

Contact: Eva Li
Phone: + 86 (215) 881-7802
Email: eatereva@hotmail.com
Address: Shanghai SUNGO Management Consulting Co., Ltd. Room 1401, Dongfang Building, 1500# Century Ave, Shanghai, 200122 CHN

3. Date Prepared – Nov 22nd, 2022

4. Device Information

Trade name:	Disposable Automatically Retractable Safety Syringes (with detachable needle)
Common name:	Syringe, Antistick Piston Syringe
Classification name:	Piston Syringe

5. Predicate Device Information

Trade Name: AUTOMATICALLY RETRACTABLE SAFETY SYRINGES WITH FIXED NEEDLE
510(K) Number: K141640
Company: SHANTOU WEALY MEDICAL INSTRUMENT CO., LTD.

6. Indications for use

The Automatically Retractable Safety Syringes with detachable needle devices are indicated for use where a safe and reliable method for intramuscular and subcutaneous injection of medication in a patient is desired.

7. General Description of the Device and principle of operation

The Disposable Automatically Retractable Safety Syringes (with Detachable Needle) devices are piston syringes, intended for medical purpose and consist of a calibrated hollow barrel and a movable plunger. The syringe works like a conventional hypodermic syringe except that the contaminated needle is retracted inside the syringe immediately after patient injection. The needle retracting mechanism is activated by a spring action mechanism after injection is completed. The exposed needle remains safely inside the syringe plunger for disposal. The Disposable Automatically Retractable Safety Syringes (with Detachable Needle) devices are sterile, single use, disposable and non-reusable.

Disposable Automatically Retractable Safety Syringes (with Detachable Needle)

Needle Size		Color	Length metric system（mm）/British System(in)								
metric system	British System		6 1/4	8 5/16	13 1/2	16 5/8	19 3/4	20 4/5	25 1	32 1 1/4	38 1 1/2
0.30	30G	Yellow									
0.33	29G	Red									
0.36	28G	Blue green									
0.40	27G	Medium Grey									
0.45	26G	Brown									
0.50	25G	Orange									
0.55	24G	Purple									
0.60	23G	Deep Blue									
0.70	22G	Black									
0.80	21G	Deep Green									
0.90	20G	Yellow									
1.20	18G	Pink									
1.60	16G	White									
Syringe Sizes			0.5ml, 1ml, 3ml, 5ml, 10ml, 20ml								

8. Comparison with predicate device

The table below compares the intended use and technological characteristics of the subject and predicate device

Device	**Proposed Device**	**Predicate Device K141640**	**Comparison**
Manufacturer	Shantou Wealy Medical Instrument CO.,Ltd.	Shantou Wealy Medical Instrument CO.,Ltd.	Same
Indications for use	The Automatically Retractable Safety Syringes	The Automatically Retractable Safety Syringes	Same
	with Detachable Needle devices are indicated for use where a safe and reliable method for intramuscular and subcutaneous injection of medication in a patient is desired.	with Fixed Needle devices are indicated for use where a safe and reliable method for intramuscular and subcutaneous injection of medication in a patient is desired.	

Environment of use	Hospital	Hospital	Same
Proprietary/trade name	Disposable Automatically Retractable Safety Syringes (with detachable needle)	Automatically Retractable Safety Syringes with Fixed Needle	—
Product code	MEG, FMI, FMF	MEG, FMI, FMF	Same
Intended users	Medical professionals	Medical professionals	Same
barrel dimensions	0.5ml barrel length: 83.42mm 1ml barrel length: 83.42mm 3ml barrel length: 72.26mm 5ml barrel length: 73.62mm 10ml barrel length:92.36mm 20ml barrel length: 111.72mm	0.5ml barrel length: 82.10mm 1ml barrel length: 82.10mm 3ml barrel length: 72.83mm 5ml barrel length: 73.62mm 10ml barrel length: 87.36mm 20ml barrel length: 106.58mm	Different: The difference in specification does not raise different questions of safety and effectiveness.
plunger dimensions	0.5ml plunger length: 95.51mm 1ml plunger length: 95.51mm 3ml plunger length: 88.23mm 5ml plunger length: 86.80mm 10ml plunger length: 104.12mm 20ml plunger length: 128.62mm	0.5ml plunger length: 94.00mm 1ml plunger length: 94.00mm 3ml plunger length: 86.80mm 5ml plunger length: 86.80mm 10ml plunger length: 100.02mm 20ml plunger length: 126.60mm	Different: The difference in specification does not raise different questions of safety and effectiveness.
needle sheath dimensions	39~57mm (subject to the length of the needle tube)	55mm	Different: The difference in specification does not raise different questions of safety and

			effectiveness.
needle length	6-38mm	6-38mm	Same
hub/needle bond strength （N）	11, 22, 34, 40, 44, 54, 69, 69	11, 22, 34, 40, 44, 54, 69, 69	Same
color	Barrel color: transparent Plunger color: white Needle sheath color: transparent Needle hub color see below.	Barrel color: transparent Plunger color: white Needle sheath color: transparent Needle hub color see below.	Same
shelf life	3 years	3 years	Same
Principle of Operation	It has a detachable needle with a dedicated fitting. The syringe works like a conventional hypodermic syringe except that the contaminated needle is retracted inside the syringe immediately after patient injection. The needle retracting mechanism is activated by a spring action mechanism after injection is completed. The exposed needle remains safely inside the empty syringe barrel for disposal.	It is an integrated needle and piston syringe. The syringe works like a conventional hypodermic syringe except that the contaminated needle is retracted inside the syringe immediately after patient injection. The needle retracting mechanism is activated by a spring action mechanism after injection is completed. The exposed needle remains safely inside the empty syringe barrel for disposal.	**Similar:** The proposed device and predicate device has the similar Principle of Operation. Difference is proposed device has detachable needle, and the predicate device has fixed needle. The device meet the requirement of ISO80369-7:2018. It do not raise questions of safety and effectiveness.
syringe type	Plunger, anti-stick with hypodermic needle	Plunger, anti-stick with hypodermic needle	Same
Safety Features	Active safety feature, automatically activated when injection is finished	Active safety feature, automatically activated when injection is finished	Same
tip type	Tri-Beveled Tip	Tri-Beveled Tip	Same
volume	0.5ml, 1ml, 3ml, 5ml, 10ml, 20ml	1, 3, 10 ml	Different: The difference in specification does not raise different questions of safety and effectiveness.
needle length	Tolerances on length comply to ISO 7864	Tolerances on length comply to ISO 7864	Same
needle gauge	30G, 29G, 28G, 27G, 26G, 25G, 24G, 23G, 22G, 21G,	30G, 29G, 27G, 26G, 25G, 24G, 23G, 22G, 21G, 20G	Different: The difference in

		20G, 18G, 16G		specification does not raise different questions of safety and effectiveness.
needle tip configuration		11°+- 2° /17°+- 2°	11°+- 2°	Different: The difference in specification does not raise different questions of safety and effectiveness.
nozzle type		Needle hub Luer connector; Needle & syringe separable	Needle & syringe not separable	Different: The difference meet the requirement of ISO80369-7:2018. It do not raise questions of safety and effectiveness.
material	Barrel	PP	PP	Same
	Plunger	PP	PP	
	Piston	Isoprene rubber	Isoprene rubber	
	Needle Hub	PP	PP	
	Needle	Stainless Steel	Stainless Steel	
	Needle Sheath	PE	PE	
	O-ring	Silicone	Silicone	
Biocompatibility		Cytotoxicity Sensitization Irritation Systemic Toxicity Haemocompatibility	Cytotoxicity Sensitization Irritation Systemic Toxicity Haemocompatibility	Same
Sterilization level and method		SAL 10^{-6} EO sterilization according to ISO 11135	SAL 10^{-6} EO sterilization according to ISO 11135	Same

Comparison Summary:
The indication for use of the proposed device and predicate device is same.
The proposed and predicate device have different technological features as noted in the table above. These technological differences do not raise different questions of safety or effectiveness.

9. Non-Clinical Tests performed on the subject device

The proposed devices were tested per the following standards, to evaluate its performance.
• ISO7886-1:2017 Sterile hypodermic syringes for single use - Part 1: Syringes for manual

use

- Limits for acidity or alkalinity
- Limits for extractable metals
- Lubricant
- Tolerance on graduated capacity
- Scale
- Numbering of scales
- Position of Scale
- Barrel dimensions
- Barrel flanges
- Plunger stopper/plunger assembly
- Conical fitting
- Position of nozzle on end of barrel
- Nozzle lumen
- Dead space
- Freedom from air and liquid leakage past plunger stopper
- Force to operate the piston
- Fit of plunger stopper/plunger in barrel

• ISO 7886-4:2006 Sterile hypodermic syringes for single use -- Part 4: Syringes with re-use prevention feature

- Self-destructive performance

• ISO7864:2016 Sterile hypodermic needles for single use

- Cleanliness
- Limits for acidity and alkalinity
- Limits for extractable metals
- Size designation
- Color coding
- Needle tube
- Freedom from defects
- Lubricant
- Needle point
- bond between hub and needle tube
- Patency of lumen
- Fragmentation test for medical needles
- Determination of flow rate through the needle

• ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices.

- Surface finish and visual appearance testing
- Cleanliness
- Limits for acidity and alkalinity
- Size designation
- Dimensions
- Stiffness
- Resistance to breakage

- ▶ Resistance to corrosion

• ISO 23908:2011 Sharps Injury Prevention

- ▶ Force applied on the plunger to activate the retractable mechanism
- ▶ Testing simulated clinical use

• ISO80369-7:2018 Small-bore connectors for liquids and gases in healthcare applications- Part 7: Connectors for intravascular or hypodermic applications

- ▶ Fluid leakage
- ▶ Sub-atmospheric Pressure Air Leakage
- ▶ Stress Cracking
- ▶ Resistance to Separation from Unscrewing
- ▶ Resistance to Separation from Axial Load
- ▶ Resistance to Overriding

• Accelerated aging testing
• Package verification
• Simulated transportation testing

10. Biocompatibility

Test	Standards
Cytotoxicity Sensitization Irritation Systemic Toxicity Haemocompatibility	ISO 10993-4: 2017 Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity ISO 10993-10:2002/Amd1:2006 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization ISO 10993-11:2006 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

- USP<788> Particulate matter in injection
- USP42-NF 37<151> Pyrogen Test
- Ethylene Oxide(EO) residue test
- Ethylene Oxide(EO) sterilization validation

11. The Simulated Clinical Study Summary

Simulated clinical testing on the sharps injury prevention features was conducted as recommended in FDA guidance document for Industry and FDA Staff: Medical Devices with Sharps Injury Prevention Features. It can support a conclusion that 99% reliability of device activation is achievable.

12. Conclusion:

Based on the Indications for use, technology characteristics, and performance testing, the subject device and the predicate devices are substantially equivalent.