



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

June 28, 2016

JeeSung Medical Co., Ltd.
% Mr. Peter Chung
Plus Global
300 Atwood Street,
Pittsburgh, Pennsylvania 15213

Re: K152606
Trade/Device Name: Jeesung Safety Syringe and Single Use Needles
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: May 9, 2016
Received: May 18, 2016

Dear Mr. Chung:

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 yours,

 Tina Kiang
-S

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)

K152606

Device Name

Jeesung Safety Syringe and Single Use Needles

Indications for Use (Describe)

Jeesung safety syringe and single use needles is a sterile, single-use, disposable and non-reusable, manual retractable safety syringe intended for injection of fluids into the body, while reducing the risk of sharps injuries and the potential for syringe reuse.

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."

510(k) Summary

[as required by 807.92]

1. Applicant

- 1) Company: JeeSung Medical Co.,Ltd.
- 2) Address: 54, Mujini 1-gil, Daedeok-gu, Daejeon, Korea
- 3) Tel: 82-42-932-6061
- 4) Fax: 82-42-932-6063
- 5) Contact Person: Peter Chung,
- 6) Tel: 412-687-3976
- 7) Email: peterchung210@gmail.com
- 8) Date of Preparation: June 22, 2016

2. Device Information

- 1) Trade Name: Jeesung Safety Syringe and Single Use Needles
- 2) Common Name: Syringe, Antistick Piston Syringe
- 3) Classification Name: Piston Syringe
- 4) Product Code: MEG
- 5) Regulation Number: 880.5860
- 6) Class of device: Class II
- 7) Panel: General Hospital

3. Predicate Device

K142435 3S Safety Syringe with/without Needle

4. Device Description

Jeesung Safety Syringe and Single Use Needles is an integrated needle and piston syringe with an anti-needle-stick mechanism. There is a swell on the top of inside barrel, which can be used to fix the hub of needle to the top of inside barrel. Four legs on the bottom of hub are caught on the swell part on the top of inside barrel when the hub is pulled.

After using this syringe (such as injecting medicine into body etc.), the hub of needle is pulled back to the inside of the barrel. Because the four legs of hub is bound to the top of the plunger which has a smaller swell part than the top of inside barrel for being caught. Therefore, by pushing plunger until it makes a binding sound, the hub can follow with the plunger. Then the plunger is broken off and the needle cannot be come out of the barrel. This renders the needle unusable and safe from accidental needle sticks.

Jeesung Safety Syringe and Single Use Needles has syringe capacity of 3cc attached with 18-30 gauge and the length of the needle (8mm, 10mm, 13mm, 16mm, 19mm, 25mm, 32mm, 38mm).

5. Indication for Use

Jeesung safety syringe and single use needles is a sterile, single-use, disposable and non-reusable, manual retractable safety syringe intended for injection of fluids into the body, while reducing the risk of sharps injuries and the potential for syringe reuse.

6. Predicate Device Comparison Table

Comparison table

Category	JeeSung Medical Co.,Ltd	Sincere Medical Device Co., Ltd.
Element of Comparison	Submission Device (K152606)	Predicate Device K142435
Regulation no.	880.5860	880.5860
Product code	MEG	MEG
Common name	Syringe, Antistick Piston Syringe	Syringe, Antistick Piston Syringe
Class	Class II	Class II
Indication for use	Jeesung safety syringe and single use needles is a sterile, single-use, disposable and non-reusable, manual retractable safety syringe intended for injection of fluids into the body, while reducing the risk of sharps injuries and the potential for syringe reuse.	The 3S Safety Syringe with/without Needle is a sterile, single-use, disposable and non-reusable, manual retractable safety syringe intended for injection of fluids into the body, while reducing the risk of sharps injuries and the potential for syringe reuse.
Principle of Operation	There is a swell on the top of inside barrel, which can be used to fix the hub of needle to the top of inside barrel. Four legs on the bottom of hub are caught on the swell part on the top of inside barrel when the hub is pulled. After using this syringe (such as injecting medicine into body etc.), the hub of needle is pulled back to the inside of the barrel. Because the four legs of hub is bound to the top of the plunger which has a smaller swell part than the top of inside barrel for being caught. Therefore, by pushing plunger until it makes a binding sound, the hub can follow with the plunger. Then the plunger is broken off and the needle cannot be come out of the barrel. This renders the needle unusable and safe from accidental needle sticks.	The needle is contained within the syringe barrel. After standard techniques for injection, the plunger is withdrawn completely into the barrel and snapped off and the needle is contained within the puncture-resistant barrel. This renders the needle unusable and safe from accidental needle sticks.
Syringe capacity	3cc	Various Sizes (smallest 0.5cc, largest 10cc)
Lubricant for Barrel	Silicone Oil	Silicone Oil
Barrel transparency	Transparent and Clear	Transparent and Clear
Gradation Legibility	Legible	Legible
Product configuration	Barrel Plunger Gasket Needle Hub Needle	Barrel Plunger Piston Needle Hub Needle

		Needle Protect cap	Needle Sheath
Material	Barrel	Polypropylene	Polypropylene
	Plunger	Polypropylene	Polypropylene
	Piston(Gasket)	Elastomer	Elastomer
	Needle hub	Polycarbonate	Polypropylene
	Needle	Stainless steel	Stainless Steel
	Needle sheath (protect cap)	Polypropylene	Polypropylene
Needle Gauge and Length	Needle gauge (18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30G) Needle length (8, 10, 13, 16, 19, 25, 32, 38mm)	Needle gauge (18, 19, 20, 21, 22, 23, 24, 25, 27, 28, 29, 30, 31G) Needle length (8, 9, 11, 13, 16, 25, 32, 38mm)	
Lubricant for Needle	Silicone Oil	Silicone Oil	
Sharp Injury Prevention Features	Manual Retractable	Manual Retractable	
Performances	Conforms to ISO7864 ISO7886	Conforms to ISO7864 ISO7886	
Biocompatibility test	Conforms to ISO10993 (ISO10993-4, ISO10993-5, ISO10993-10, ISO10993-11)	Conforms to ISO10993	
Labeling	Meet the requirements of 21 CFR Part 801	Meet the requirements of 21 CFR Part 801	
Sterilization information	E.O gas sterilization Assurance level : 10 ⁻⁶	E.O gas sterilization Assurance level : 10 ⁻⁶	

The proposed and predicate devices are the same indications for use, principle of operation, Lubricant for Barrel, product configuration, lubricant for needle, sharp injury prevention feature. The proposed device syringe capacity includes 3cc which are within the range of the predicate syringe 0.5cc to 10cc. The subject device needle sizes are 18-30G and needle length 8, 10, 13, 16, 19, 25, 32, 38mm which are within the range of predicate needle gauge 18-31G and needle length 8-38mm. Therefore, these differences do not affect substantially equivalency between the proposed devices and predicate device.

7. Performance Data

No	Test item	Test method	
		Test criteria	Test result (pass / failure)
1	Cytotoxicity test	ISO10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity, Test on extracts method	
		Non-cytotoxicity	Non- cytotoxicity (Pass)
2	Hemolysis test	ISO10993-4: 2002(E) Biological evaluation of medical devices – Part 4: Selection for tests for interactions with blood, Evaluation of hemolytic properties of medical and their components	
		Non-hemolytic	Non-hemolytic (Pass)
		ISO10993-4: 2002/Amd.1 : 2006 Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood AMENDMENT 1 Annex C.6 Hemolysis testing General considerations	
		Refer to test report	There was non-hemolytic.
3	Acute systematic toxicity test	ISO10993-11: 2006(E) Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity, 5. Acute systemic toxicity	
		No dead animals No strange reaction animals	Non-acute systemic toxicity (Pass)

4	Skin sensitization test	ISO10993-10: 2010(E), Biological evaluation of medical devices Part 10: Test for Irritation and sensitization. Guinea pig Maximization test (GPMT)	
		Non-skin hypersensitivity reaction	There was non-skin hypersensitivity reaction. (Pass)
5	Pyrogen Test	ISO 10993-11 :2006, Biological evaluation of medical devices, Test for systemic, Annex(F) Information on material-mediated pyrogens	
		Non-pyrogenicity	Non-pyrogenicity (Pass)
		USP 38 NF 33 <85> Bacterial Endotoxin test "Gel clot method"	
		Concentration of the reaction solution is determined as (-)	As a result of the reaction, all the concentration of the test solution were determined as (-). Therefore, endotoxin concentration of the test sample is less than 4.0 EU/device.
6	Intracutaneous reactivity test	ISO 10993-10 :2010(E), Biological evaluation of medical devices, Test for irritation and skin sensitization, Animal Intracutaneous(intradermal) reactivity Test.	
		Non-intracutaneous reactivity	There was non-intracutaneous reactivity. (Pass)
7	Particulate matters	USP <788> Particulate Matter in Injections	
		Particles does not greater than 10 μ m and greater than 25 μ m	Particles greater than 10 μ m – 0 particle Particles greater than 25 μ m – 0 particle

Based on the above testing results, the subject devices are biocompatible.

		Test items	Result summary
1	Syringe (ISO7886-1 : 1993)	Inner/outside and structure	Surface is smooth / no particle and foreign substance
		Graduated scale	Dead space (0.06ml), capacity (2.19ml), Graduation lines were evenly spaces, overall length of scale (32.0mm)
		Barrel	The length of the barrel is such that the syringe has a maximum usable capacity of at least 10% more than the nominal capacity
		Piston(gasket)/plunger assembly	Design, fit of piston in barrel, fiducial line are suitable
		Liquid leakage	Pressure test – no leaked water / aspirate test – no leaked air
		Lubricant	The quantity of lubricant :0.18mg/cm ³
2	Needle (ISO7864 : 1993)	Inner/outside and structure	No scratch, no crack, smooth, no foreign materials, sharpened needle edge
		Measurement	Outside diameter of needle : 0.645mm for 0.6000-0.673 criteria / length of needle : 24.7mm for 25(+1.5/-2.5) criteria
		Elasticity test	Needle returned after remove weight.
		Flexural rigidity	Needle was not broken.
		Draw test	The union of the hub and needle tube was not broken.
3	Stimulated Clinical Use Testing report	As a result of a simulated clinical use study using 500 subject devices, the number of failure of the subject devices safety feature is not founded and resulted to zero failure of the protective feature.	

Based on the result of the above syringe, needle testing and stimulated clinical use testing, the proposed devices are satisfied with all the acceptance criteria.

8. Conclusion

Both subject and predicate devices have the same Indications for Use. Based on the result of the device comparison and performance data, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate device.