August 18, 2022

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

Re: K212518
Trade/Device Name: Jeesung Safety Syringe and Single Use Needles
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: MEG
Dated: July 13, 2022
Received: July 20, 2022

Dear Peter 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. 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,

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)*
K212518

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.

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510(k) Summary

1. Submitter information

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) Prepared date : December 30, 2021
6) Contact Person: Peter Chung, 412-687-3976
7) Contact person address : 300, Atwood Street, Pittsburgh, PA, 15213, USA
8) Submission date : December 30, 2021

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

1) Trade Name: Jeesung Safety Syringe and Single Use Needles (K152606)
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

4. Reason for Special 510(k) Submission

The basis of this submission is to modify the capacity of syringe of Jeesung Safety Syringe And Single Use Needles.

5. 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 is available in the combinations of the following sizes and capacities:

Syringe Capacity(cc) : 1cc and 3cc
Needle Gauge(G) : 23G, 25G
The length of the needle(mm) : 8mm, 10mm, 13mm, 16mm, 19mm, 25mm, 32mm, 38mm

6. Intended 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.

7. Comparison of Technological characteristic with the predicate device

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence :

- Indications for use – The predicate and subject device have identical indications for use; both devices are indicated for injection of fluids into the body, while reducing the risk of sharps injuries and the potential for syringe reuse.
- Materials – The predicate and subject devices are both made of medical grade stainless steel needles.
- Design – The predicate and subject device have equivalence design. They are both made of the same materials.
- Performance Testing – Both the predicate and subject device were subjected to performance testing under the MEG product code to support substantial equivalence in terms of performance.

The table below provides comparison of key features of the subject and predicate devices.

Element of Comparison	**Predicate Device** Jeesung safety syringe and single use needles	**Subject Device** Jeesung safety syringe and single use needles	**Comparison**
510(k) Number	K152606	K212518	N/A
Regulation no.	880.5860	880.5860	SAME
Product code	MEG	MEG	SAME
Common name	Syringe, Antistick Piston Syringe	Syringe, Antistick Piston Syringe	SAME
Class	Class II	Class II	SAME
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.	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.	SAME
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.	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.	SAME
Syringe capacity	3cc	1cc, 3cc	Different; 1cc is added for the subject device
Lubricant for Barrel	Silicon Oil	Silicon Oil	SAME

Barrel transparency		Transparent and Clear	Transparent and Clear	SAME
Product configuration		Barrel Plunger Gasket Needle Hub Needle Needle Protect cap	Barrel Plunger Gasket Needle Hub Needle Needle Protect cap	SAME
Material	Barrel Plunger Piston(Gasket) Needle hub Needle Needle sheath (protect cap)	Polypropylene Polypropylene Elastomer Polycarbonate Stainless steel Polypropylene	Polypropylene Polypropylene Elastomer Polycarbonate Stainless steel Polypropylene	SAME
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 (23G, 25G) Needle length (8, 10, 13, 16, 19, 25, 32, 38mm)	Similar
Lubricant for Needle		Silicon Oil	Silicon Oil	SAME
Sharp Injury Prevention Features		Manual Retractable	Manual Retractable	SAME
Performances		Conforms to ISO7864, ISO7886	Conforms to ISO7864, ISO7886	SAME
Biocompatibility test		Conforms to ISO10993 (ISO10993-4, ISO10993-5, ISO10993-10, ISO10993-11)	Conforms to ISO10993 (ISO10993-4, ISO10993-5, ISO10993-10, ISO10993-11)	SAME
Labeling		Meet the requirements of 21 CFR Part 801	Meet the requirements of 21 CFR Part 801	SAME
Sterilization information		E.O gas sterilization Assurance level : 10^{-6}	E.O gas sterilization Assurance level : 10^{-6}	SAME

There are some differences in syringe capacity and needle gauge between the predicate device and the subject device. The subject device is available in 1cc and 3cc. In case of needle gauge, only 23G and 25G are available for the subject device. To confirm that these differences do not impact the performance and safety of the predicate device, performance test and biocompatibility test were carried out. Test results were acceptable. Therefore, we can conclude that the subject device is substantially equivalent to the predicate device.

8. Performance Data

The following performance testing has been conducted to support determination of substantial equivalence of the subject device. This includes biocompatibility testing of the component, sterilization validation, shelf-life study, performance testing as required under the MEG product code.

Needle performance Testing

- Appearance
- Limits for acidity or alkalinity
- Limits for extractable metals
- Lubricant
- Graduated scale
- Numbering of scales
- Barrel
- Plunger stopper/plunger assembly
- Nozzle
- Dead space

- Freedom from liquid/air leakage
- Force to operate the piston
- Fit of plunger stopper/plunger in barrel

Biocompatibility Testing
- Cytotoxicity test
- Intracutaneous Reactivity Test
- Acute Systemic Toxicity Test
- Pyrogen Test
- Hemolysis Test
- Skin Sensitization study
- Particulate matters

Sterilization Validation
- EO Sterilization Validation in accordance with ISO 11135

Shelf Life Study
- Accelerated Aging
- Packaging Integrity test

Packaging Process Validation Study
- Sealing condition

Shipping Validation Study
- ISTA 2018 Integrity Test Procedure 2A, ASTM D4169-16.

Clinical Testing
- Clinical testing was not required to support substantial equivalence.

8. Conclusion

The proposed device has identical indications for use to the predicate device. Both devices have similar technological characteristics such as safety features and materials of manufacture. Appropriate performance testing was conducted to support determination of substantial equivalence of the proposed device. The results of this testing demonstrates that the subject device is substantially equivalent in safety and performance to the predicate device.