Jeil Tech Co., Ltd.
% Peter Chung
President
Plus Global
300, Atwood
Pittsburgh, Pennsylvania 15213

September 19, 2022

Re: K213013
Trade/Device Name: Sterile Single-use LDV Syringe, CHOICARE Sterile Single-use LDV Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QNQ, FMI
Dated: August 17, 2022
Received: August 17, 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 M. 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)*
K213013

Device Name
Sterile Single-use LDV Syringe, CHOICARE Sterile Single-use LDV Syringe

Indications for Use *(Describe)*
STERILE SINGLE USE LDV SYRINGE/CHOICARE STERILE SINGLE USE LDV SYRINGE is intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin.

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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K213013 - 510(k) Summary

[as required by 807.92(c)]

1. **Date of Preparation:** September 19, 2022

2. **Applicant**
   1) Company: Jeil Tech Co., Ltd.
   2) Address: 190, Maesilro, Sojeongmyeon, Sejong-si, Republic of Korea
   3) Tel : +82-44-862-2656
   4) Fax : +82-44-826-2657
   5) Contact person : Peter Chung, 412-512-8802
   6) Contact person address : 300 Atwood Street, Pittsburgh, PA, 15213, USA
   7) Submission date: Sep. 10, 2021
   8) Prior related submission : Not applicable

3. **Subject Device Information**
   1) Trade name : STERILE SINGLE USE LDV SYRINGE, CHOICARE STERILE SINGLE USE LDV SYRINGE
   2) Common name : Disposal syringe with needle
   3) Classification name : Piston syringe/ Needle, Hypodermic, Single Lumen
   4) Product code : QNQ, FMI
   5) Regulation number : 880.5860
   6) Class of device : Class II
   7) Panel : General hospital

4. **Predicate Devices**
   Trade name: Safety Syringe With Permanently Attached Needle
   Premarket Notification: K192551
   Manufacturer: Jiangsu Caina Medical Co., Ltd.

5. **Device description**
   A Disposable Syringe with Needle is a device intended for medical purposes that consists of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a hypodermic single lumen needle which is permanently attached. The device is used to inject fluids into, or withdraw fluids from, the body. This is a single-use device. This product is packed by sterile paper and sterilized by E.O gas.

6. **Intended Use:**
   STERILE SINGLE USE LDV SYRINGE/CHOICARE STERILE SINGLE USE LDV SYRINGE is intended to be used for medical purposes to inject fluids to the body.

7. **Indication for Use:**
   STERILE SINGLE USE LDV SYRINGE/CHOICARE STERILE SINGLE USE LDV SYRINGE is intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin.

8. **Performance data:**
   1) Bench tests were performed. Bench testing included biocompatibility, mechanical testing, sterility testing including EO residues. The tests demonstrated that the device performs in a substantially equivalent manner to the predicate device. The devices conform to ISO 7886-1:2017, ISO 9626:2016, ISO 7864:2016, and ISO 23908:2011. For example, the following bench testing is performed to demonstrate the functionality is substantially equivalent.

Requirement – Test (ISO 7886-1)	Result
Visual check	Pass
Dimension (out diameter of the needle tube)	Pass
Length of the needle tube	Pass
Nozzle	Pass
Tightness	Pass
Piston/Plunger Assembly	Pass

Requirement – Test (ISO 7864)	Result
Elasticity	Pass
Flexural strength	Pass
Pullout	Pass
Requirement – Test (ISO 9626)	
Stiffness	Pass
Resistance to breakage	Pass
Resistance to corrosion	Pass

2) Dead volume

In accordance with the FDA's requirements, to claim that the product has the aspect "Low Dead Volume" the specification for syringe and needle combined dead volume shall be satisfied with the following criteria. (< 0.0284ml)

According to the provided testing result, STERILE SINGLE USE LDV SYRINGE, CHOICARE STERILE SINGLE USE LDV SYRINGE conforms this requirement.

3) Biocompatibility

Biocompatibility of the STERILE SINGLE USE LDV SYRINGE, CHOICARE STERILE SINGLE USE LDV SYRINGE was evaluated in accordance with ISO 10993-1:2018 for the body contact category of "External communication device – Blood path indirect" with a contact duration of "Limited (< 24 hours)". The following tests were performed, as recommended: Cytotoxicity; Skin sensitization; Hemolysis; Intracutaneous reactivity; Acute systemic toxicity;

Test item	Test method / Test criteria	Test result
Cytotoxicity test	When it was tested accordingly to ISO 10993-5, tests for in vitro cytotoxicity-Test on extracts method, it should satisfy the requirements.	Pass
Hemolysis test	When it was tested accordingly to ISO 10993-4, Selection off tests for interactions with blood-evaluation of hemolytic properties of medical devices and medical device materials, it should satisfy the requirements.	Pass
Intracutaneous reactivity test	When it was tested accordingly to ISO 10993-10, Tests for irritation and skin sensitization-Animal intracutaneous (Intradermal) reactivity test, it should satisfy the requirements.	Pass
Skin sensitization test	when it was tested accordingly to ISO 10993-10, Tests for irritation and skin sensitization-Guinea pig maximization test (GPMT), it should satisfy the requirements.	Pass
Acute systemic toxicity test	When it was tested accordingly to ISO 10993-11, Tests for systemic toxicity-Acute systemic toxicity, it should satisfy the requirements.	Pass
Pyrogen Test	When it was tested accordingly to ISO 10993-11, Tests for systemic toxicity-Information on material-mediated pyrogens, it should satisfy the requirements.	Pass
LAL Test	USP39 <85>, Bacterial Endotoxins Test	Pass
Particulate Matter Injection	USP <788>, Particulate Matter for Injections (Method 1 Light Obscuration Particle Count Test). Test result should satisfy the requirements described in the USP <788>.	Pass

4) Sterility and LAL test

The sterilization method has been validated to ISO11135, which has thereby determined the routine control and monitoring parameters. The testing is performed according to the following standards:

#	Test item	Test standard	Test result
1	LAL test	USP39 <85>, Bacterial Endotoxins Test (Unit : EU/Device)	Pass
2	E.O sterilization validation	According to ISO 11135:2014 E.O 30%, CO_2 70% Temperature: 50 ±7℃ Exposure time: 5 hours	Pass
3	Sterility test	According to ISO 11737-2	Pass
4	E.O Residual test	Under the conditions of ISO 10993-7:2008, Ethylene oxide sterilization residuals, the test articles should meet the test requirements.	Pass

5) Needle injury test

#	Test item	Test standard	Test result
1	Needle penetration force	ISO 23908: 2011 Sharps injury protection	Pass
2	Pull-out force	ISO 23908: 2011 Sharps injury protection	Pass
3	Needle cap removal force	ISO 23908: 2011 Sharps injury protection	Pass
4	Activation (locking) force	ISO 23908: 2011 Sharps injury protection	Pass
5	Unlocking force	ISO 23908: 2011 Sharps injury protection	Pass

6) Substantially Equivalent (SE) Comparison

Table 1. Comparison table

Manufacturer	Jeil Tech Co., Ltd.		Jiangsu Caina Medical Co., Ltd.		Remark
Item	Proposed device		Predicate device		
510(K) No.			K192551		N/A
Indication for use	STERILE SINGLE USE LDV SYRINGE/ CHOICARE STERILE SINGLE USE LDV SYRINGE is intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules, and liquid injection below the surface of the skin.		The Safety Syringe with permanently attached needle is intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin. The Safety sheath of Syringe is designed to aid in the prevention of needle stick injuries and reduce the potential or syringe reuse.		Same
Components	Barrel, Plunger, Piston, Safety cap		Barrel, Plunger, Piston, Safety sheath		Same
Materials	Needle cap	PE	Needle cap	PP or PE	Same
	Needle	Stainless Steel 304	Needle	Stainless Steel 304	
	Safety guard	PP	Safety mechanism	PP	
	Piston	Polyisoprene	Piston	Polyisoprene	
	Plunger	PP	Plunger	PP	
	Barrel	PP	Barrel	PP	
Capacity (Syringe volume)	0.5 1ml		0.3, 0.5, 1ml		Different #1
Nozzle type	Permanently attached		Permanently attached		Same
Needle Gauge	23, 25G		25, 26, 27, 28, 29, 30, 31G		Different #2
Needle Length	25mm		8, 10, 13, 16mm		
Needle wall type	TW		RW, TW		
Needle bevel	11°±2°		11°±2°, 15°±2°		
Needle Hub	Polypropylene (PP)		Polypropylene (PP)		Same
Principle of operation	For Manual Use Only For Single Use Only		For Manual Use Only For Single Use Only		Same

Syringe Performances	Complies with ISO 7886-1 : 2017 Sterile hypodermic syringes for single use – Part 1 : Syringes for manual use	Complies with ISO 7886-1 : 2017 Sterile hypodermic syringes for single use – Part 1 : Syringes for manual use	Same
Needle Performances	ISO 7864 : 2016 Sterile hypodermic needles for single use — Requirements and test methods ISO 9626 : 2016 Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods	ISO 7864 : 2016 Sterile hypodermic needles for single use — Requirements and test methods ISO 9626 : 2016 Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods	Same
Safety feature performance specification	1) Safety guard clamping force shall be less than 15 N 2) Needle should not be separated from safety guard until pushed vertically by 25mm.	i. The torque to lock shall be less than 10N·cm ii. The force to destroy forward shall not be less than 30N iii. The force to destroy backward shall not be less than 60N iv. The torque to unscrewing shall be greater than 20N·cm	Different #3
Biocompatibility	Conforms to the requirements of ISO 10993 series standards. Cytotoxicity Acute systemic toxicity Pyrogenicity Sensitization Irritation Hemolysis Intracutaneous reactivity Bacterial Endotoxins Particulate Matter Injection	Conforms to the requirements of ISO 10993 series standards. Cytotoxicity Acute systemic toxicity Pyrogenicity Sensitization Irritation Hemolysis Intracutaneous reactivity Bacterial Endotoxins Particulate Matter Injection	Same
Sterilization	E.O Sterilized	E.O Sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same
Principle of operation	The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and expel the fluids through the connector to the patient.	The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and expel the fluids through the connector to the patient.	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same

2. Equivalence discussion

Different 1 - Capacity (Syringe volume)

The Syringe volume for proposed devices is different from the predicate devices 1.
This difference does not affect intended use and does not raise new questions of safety and effectiveness. Differences in syringe volume between the predicate and subject device were addressed through ISO 7886-1:2017 performance testing.

Different 2 - Needle gauge, length, wall type and bevel

The needle gauge and length for proposed devices is different from the predicate devices. This difference does not affect intended use and does not raise new questions of safety and effectiveness. Differences in needle length and gauge between the predicate and proposed device were addressed through ISO 7864:2016 and ISO 9626:2016 performance testing.
The needle wall type for predicate device is differ from proposed device. However, the performance test for proposed device has been conducted and the test result conform with requirements of ISO 7864:2016 and ISO 9626:2016 standards. Also proposed device's needle wall type is included in range of predicate device's needle

wall type. According to 510(k) summary of predicate device, it has Regular(RW) and thin wall(TW) type. Subject device only has a thin wall type needle, which does not affect its intended use, and does not raise any new questions of safety and effectiveness.
The needle bevel for proposed devices is different from the predicate device. This difference does not affect intended use. In addition, subject device is conforming to recommendation by the relevant standard(ISO 7864:2016, section 4.11 Needle point). The differences in needle bevel between the predicate and subject device were addressed through ISO 7864:2016 and ISO 9626:2016 performance testing.

Different 3 – Safety feature performance specification

The Safety feature performance specifications for predicate device is different from the predicate device. However, the safety feature performance test for proposed device has been evaluated and the test result conforms to requirements of ISO 23908:2011 standards. Therefore, the differences on configuration and materials does not affect substantially equivalence.

3. Substantially Equivalent (SE) Conclusion

The STERILE SINGLE USE LDV SYRINGE of Jeil Tech Co., Ltd. is substantially equivalent to the legally marketed predicate device.