May 31, 2023

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

Re: K213010
Trade/Device Name: FEELject LDV (Low dead volume) syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QNQ, FMI
Dated: April 28, 2023
Received: May 1, 2023

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)*
K213010

Device Name
FEELject LDV(Low dead volume) Syringe

Indications for Use *(Describe)*
FEELject LDV(Low dead volume) Syringe is intended for use to inject fluid into or withdraw fluids from the parts of body 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K213010 - 510(k) Summary

[as required by 21 CFR 807.92(c)]

1. Applicant

1) Company: Feeltech Co., Ltd.
2) Address: 3, 4 Floor, Standard Factory 2-dong, 15, Jayumuyeok2-gil, Gunsan-si, Jeollabuk-do, Korea
3) Tel : +82-63-468-6626~8
4) Fax : +82-63-468-6623
5) Prepared date : May 18, 2023
6) Contact person : Peter Chung, 412-512-8802
7) Contact person address : 300 Atwood Street, Pittsburgh, PA, 15213, USA

2. Subject Device Information

1) Trade name: FEELject LDV(Low dead volume) Syringe
2) Common name : Disposal syringe with needle
3) Classification name : Piston syringe
4) Product code : QNQ, FMI
5) Regulation number : 21 CFR 880.5860
6) Class of device : Class II
7) Panel : General hospital

3. The legally marketed device to which we are claiming equivalence

Syringe, K192551, Jiangsu Caina Medical Co., Ltd.

4. 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. It is made of plastic and silicone materials that allows for smooth plunger movement, and manually operated. This is a single-use device. This product is packed by sterile paper and sterilized by E.O gas.

5. Intended Use:

This product is intended for use to inject fluids into or withdraw fluids from parts of the body below the surface of the skin.

6. Comparison Table

Table 1. Comparison table of proposed to predicate device

Manufacturer		FeelTech Co., Ltd.	Jiangsu Caina Medical Co., Ltd.	Remark
Item		Proposed device	Predicate device	
510(K) No.		K213010	K192551	N/A
Product		FEELject LDV Syringe	Syringe with permanently attached needle	
Intended use		This product is intended for use to inject fluids into or withdraw from parts of the body below the surface of the skin	This device is intended for use to inject fluids into or withdraw from parts of the body below the surface of the skin	Same
Components		Barrel, Plunger, Plunger rod Needle, needle cap	Barrel, Plunger, Plunger rod Needle, needle cap	Same
Nozzle type		Permanently attached	Permanently attached Luer-slip/Luer-lock	Different #1
Material	Barrel	Polypropylene (PP)	Polypropylene (PP)	Same
	Plunger	Polypropylene (PP)	Polypropylene (PP)	
	Piston	Rubber	Rubber	
	Needle hub	Polypropylene (PP)	Polypropylene (PP)	
	Needle	SUS304	SUS304	
	Needle cap	Polypropylene (PP)	Polypropylene (PP)	
Capacity		1ml	0.3, 0.5, 1ml	Different #2
Dead space		Low dead volume (≤ 0.03 mL)	Unknown	Different #3

Principle of operation	Manual	Manual	Same
Syringe Performances[1]	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 Length	25.0, 25.4, 38.1mm	8, 10, 13 16, 20, 25mm	Different #4
Gauge	23, 25G	21, 23, 25, 26, 27, 28, 29, 30, 31G	
Needle Tip configuration	Bevel (11°±2°)	Bevel (11°±2°, 15°±2°)	
Needle wall type	TW	RW, TW	
Needle performance[1]	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
Bio-Compatibility[1]	Conforms to the requirements of ISO 10993 series standards. Cytotoxicity Acute systemic toxicity Pyrogenicity Sensitization Irritation Hemolysis Intracutaneous reactivity Bacterial Endotoxins	Conforms to the requirements of ISO 10993 series standards. Cytotoxicity Acute systemic toxicity Pyrogenicity Sensitization Irritation Hemolysis Intracutaneous reactivity Bacterial Endotoxins	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
Sterilization method	E.O Gas sterilization	E.O Gas Sterilization	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin limit[1]	20 EU / Device	20 EU / Device	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same

* Note 1: Refer to the following section (8. Performance data) for the detail descriptions of conducted testing result.

7. Equivalence Discussion

1) Different #1 – Syringe nozzle type
Subject device only has permanently attached nozzle type. However, predicate device has not only permanently attached nozzle, but also luer-lock and luer-slip. While this configuration is different from each other, the subject device's nozzle configuration is included to the predicate device. Therefore, the differences on nozzle type does not raise new questions of safety and effectiveness.

2) Different #2 – Capacity
Subject device has only one capacity configuration. (1 ml) Although predicate device has 3 configuration for the capacity (0.3, 0.5, 1 ml) this difference does not affect substantial equivalence because it is covered within the predicate submission.

3) Different #3 – Dead space
Subject device is intended to provide low dead volume (LDV), minimizing the loss of fluid left inside the syringe. Although predicate device does not have this aspect, subject device is better than its requirements for the dead space. In accordance with product code 'QNQ', this device has proved with related performance testing that it conforms to the FDA's requirements. Therefore, the differences between predicate and subject device does not affect the device's effectiveness and safety.

4) Different #4 – Needle configurations (Needle length, gauge, tip configuration, wall type)
The needle configurations (Needle length, gauge, tip configuration, wall type) for proposed devices is different from the predicate devices. However, the predicate device covers the range of needle dimensions.

Therefore, the differences on needle length and gauge does not affect safety and effectiveness.

8. Performance data evaluation

1) Performance testing – Bench

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 following bench testing is performed to demonstrate the functionality is substantially equivalent.

Requirement – Test (ISO 7886-1)	Result
Limits for extractable metals	Pass
General	Pass
Limits for acidity or alkalinity	Pass
Conical fitting	Pass
Position of nozzle on end of barrel	Pass
Tolerance on graduated capacity	Pass
Scale	Pass
Numbering of scales	Pass
Overall length of scale to nominal capacity line	Pass
Position of scale	Pass
Barrel flanges	Pass
Plunger stopper/plunger assembly	Pass
Dead space	Pass
Freedom from air and liquid leakage past plunger stopper	Pass
Force to operate the piston	Pass
Fit of plunger stopper/plunger in barrel	Pass
Unit packaging and self-contained syringe units	Pass
Quantity of silicone oil	Pass

Requirement – Test (ISO 7864)	Result
Cleanliness	Pass
Tolerances on length	Pass
Needle Point, needles with sharp tip only	Pass
Bond between hub and needle tube	Pass
Patency lumen	Pass

Requirement – Test (ISO 9626)	Result
Stiffness	Pass
Resistance to breakage	Pass
Resistance to corrosion	Pass

Requirement – Test (USP 788)	Result
Particulate matter injections	Pass

2) Biocompatibility

#	Test item	Test method / Test criteria	Result
1	Cytotoxicity	ISO 10993-5 Tests for in vitro cytotoxicity	Pass
2	Skin Sensitization Test	ISO 10993-10 irritation and skin sensitization	Pass
3	Intracutaneous Reactivity Test	ISO 10993-10 Test for irritation and skin sensitization, maximization test for delayed hypersensitivity	Pass
4	Acute Systemic Toxicity Test	ISO 10993-11 Test for systemic toxicity – Acute Systemic Toxicity	Pass
5	Pyrogen Test	ISO 10993-11 Tests for systemic toxicity, Annex(F) Information on material-mediated pyrogens.	Pass
6	Hemolysis Test	ISO 10993-4 Selection of tests for interactions with blood	Pass

3) Sterility and LAL test

#	Test item	Test standard	Result
1	LAL test	USP39 <85>, Bacterial Endotoxins Test (Unit : EU/Device)	Pass
2	Sterility test	According to ISO 11737-2	Pass
3	E.O Residual	Under the conditions of ISO 10993-7:2008, Ethylene oxide sterilization	Pass

	test	residuals, the test articles should meet the test requirements.	

Above conducted performance tests demonstrated that this device is performs in a substantially equivalent manner to the predicate device.

9. Conclusion

The device has completed testing to show that the device meets its intended use and demonstrates substantial equivalence to the predicate device, K192551. Therefore, it is concluded that the subject device, FEELject LDV (Low dead volume) Syringe is substantially equivalent to the legally marketed predicate device, K192551.