March 15, 2024

MedExel Co., Ltd.
℅ Peter Chung, President
PlusGlobal
300 Atwood Street
Pittsburgh, Pennsylvania 15213

Re: K231856
Trade/Device Name: TopFine® LDS (Low Dead Space) Syringe (2 models (TS-LDS2334, TS-LDS2534))
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QNQ
Dated: February 14, 2024
Received: February 14, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shruti N. Mistry -S

Shruti Mistry
Assistant Director, Injection Team
Division of Drug Delivery and General
Hospital Devices, and Human Factors
Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
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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)*
K231856

Device Name
TopFine® LDS (Low Dead Space) Syringe (2 models (TS-LDS2334, TS-LDS2534))

Indications for Use *(Describe)*
TopFine® LDS (Low Dead Space) 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.

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K231856- 510(K) Summary

I. Submitter

510(k) Submitter: MedExel Co., Ltd.
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Primary Contact: Peter Chung
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Secondary Contact: Juntaek Seo
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Date prepared: 15 March, 2024

II. Device Name

Device Trade Name	TopFine® LDS (Low Dead Space) Syringe (2 models (TS-LDS2334, TS-LDS2534))
Common Name	Piston syringe
Classification Name	Low Dead Space Piston Syringe
Regulation Number	21 CFR 880.5860
Product Code	QNQ

III. Legally Marketed Predicate Device

Predicate #	K213010
Predicate Trade Name	FEELject LDV (Low dead volume) syringe

IV. Device Description

The TopFine® LDS (Low Dead Space) Syringe 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 a 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 is manually operated. This is a single-use device. This product is packed by sterile paper and sterilized by Ethylene Oxide gas.

The proposed device has 2 models depending on the diameter of the needle.

No.	Model name	Diameter of needle	Length of needle
1	TS-LDS2334	23G (0.600 ~ 0.673 mm)	26.5 mm (+1.5 / -2.5 mm)
2	TS-LDS2534	25G (0.500 ~ 0.530 mm)	26.5 mm (+1.5 / -2.5 mm)

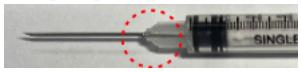
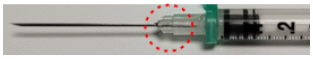
The difference between the above 2 models is only the needle diameter.

V. Indications for Use

TopFine® LDS (Low Dead Space) Syringe is intended for use to inject fluid into or withdraw fluids from the parts of body below the surface of the skin.

VI. Comparison of technological characteristics with the predicate device

Item		Proposed Device	Predicate Device	Remark
510(k) No.		K231856	K213010	-
Regulation No.		21 CFR 880.5860	21 CFR 880.5860	Same
Product Code		QNQ	QNQ, FMI	Same
Indications for Use		TopFine® LDS (Low Dead Space) Syringe is intended for use to inject fluid into or withdraw fluids from the parts of body below the surface of the skin.	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.	Same
Type of use		Prescription Use	Prescription Use	Same
Mechanism of action		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
Number of uses		Single Use Only	Single Use Only	Same
Configu-ration and materials	Needle	- Needle : SUS 304 - Cap : Polypropylene	- Needle : SUS 304 - Cap : Polypropylene	Same
	Syringe	- Barrel : Polypropylene - Plunger : Polypropylene - Gasket : Polyisoprene	- Barrel : Polypropylene - Plunger : Polypropylene - Gasket : Polyisoprene	Same
Needle Gauge		23G, 25G	23G, 25G	Same
Needle dimension – OD		23G: 0.600 ~ 0.673 mm 25G: 0.500 ~ 0.530 mm	23G: 0.600 ~ 0.673 mm 25G: 0.500 ~ 0.530 mm	Same
Needle dimension – needle length		26.5 mm (+1.5 / -2.5 mm)	25.0 mm 25.4 mm 38.1 mm	Different See note 1
Syringe nozzle type		Permanently attached	Permanently attached	Same
Syringe capacity		1 ml	1 ml	Same
Dead space		Low dead volume ≤ 0.03 ml	Low dead volume ≤ 0.03 ml	Same
Biocompatibility		According to ISO 10993-1	According to ISO 10993-1	Same
Perfor-mance	Needle	ISO 7864:2016 Sterile hypodermic needles for single use – Requirements and test methods	ISO 7864:2016 Sterile hypodermic needles for single use – Requirements and test methods	Same

		ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods	ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods	
	Syringe	ISO 7886-1:2017 Sterile hypodermic syringes for single use – Part 1: Syringes for manual use	ISO 7886-1:2017 Sterile hypodermic syringes for single use – Part 1: Syringes for manual use	Same
Sterility		Sterilized by EO Gas SAL=10^{-6}	Sterilized by EO Gas SAL=10^{-6}	Same
Endotoxin limit		20 EU/Device	20 EU/Device	Same
Labeling		Complies with 21 CFR part 801	Complies with 21 CFR part 801	Same
Physical specification		Tip type : Slip Tip 	Tip type : Slip Tip 	Same
Mechanical specification		Hub/needle bond strength (ISO 7864) 1) 23 Gauge: ≥ 34 N 2) 25 Gauge: ≥ 22 N	Hub/needle bond strength (ISO 7864) 1) 23 Gauge: ≥ 34 N 2) 25 Gauge: ≥ 22 N	Same

<u>Note 1</u>: Needle length

The needle length of proposed device is different from the needle of predicate device. In order to confirm the performance between the different needle specifications, the proposed device was verified by measuring the needle length at each time point of accelerated aging test. The proposed device was found to be substantially equivalent to the predicate device.

VII. Performance data

1. Biocompatibility Testing

In accordance with ISO 10993-1 the subject device is classified as: Externally Communicating Device, Blood Path Indirect, Limited Contact (<24hours). The following testing was conducted.

1) Cytotoxicity
2) Sensitization
3) Irritation
4) Acute Systemic Toxicity
5) Material Mediated Pyrogenicity
6) Hemolysis

Particulate matter testing was conducted in accordance with USP <788> Particulate Matter in Injection and met the USP acceptance criteria.

2. Physical Performance Testing

(1) ISO 7864:2016-Sterile hypodermic needles for single use requirements and test methods
(2) ISO 7886-1:2017-Sterile hypodermic syringes for single use Part 1: Syringes for manual use
(3) ISO 9626:2016-Stainless steel needle tubing for the manufacture of medical devices

3. Sterility, Shipping and Shelf-Life

The sterilization method is Ethylene Oxide. EO not detected (Limit of Detection: 0001), ECH- Not detected. (Limit of Detection: 0.02), validation method: Overkill Approach (e.g., Half-Cycle method), pyrogen test: Bacterial endotoxin USP <161>Medical devices -Bacterial Endotoxin and pyrogen test, USP <85> Bacterial endotoxins test.

- Package integrity testing, after environmental conditioning and simulated transportation using ASTM D4169-22, was conducted on final packaged, and sterile devices. All packaging is acceptable for protection of final finished product and sterility maintenance.

- Sterile Barrier Packaging Testing performed on the proposed device:
  - Seal peel test – ASTM F88/F88 -15
  - Dye migration- ASTM F1929-15

- Shelf life of 3 years is validated using the FDA recognized standard ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier System for Medical Devices.

4. Clinical Studies

Clinical testing was not required to support substantial equivalence.

VIII. Conclusion

The differences between the predicate device and the subject device do not raise any new or different questions of safety or effectiveness. The TopFine® LDS (Low Dead Space) Syringe (2 models (TS-LDS2334, TS-LDS2534) is substantially equivalent to the FEELject LDV (low dead volume) syringe with respect to the indications for use, target populations, treatment method, and technological characteristics.