



February 19, 2026

CMT Health Pte. Ltd.
Monica Ma
150 Beach Road, #28-05, Gateway West
Singapore, 189720, Singapore

Re: K252814

Trade/Device Name: Profoject™ Low Dead Space Syringe /Profoject™ Tuberculin Syringe;
Profoject™ Low Dead Space Syringe with Needle /Profoject™ Tuberculin
Syringe with Needle; Profoject™ Low Dead Space Syringe with Permanent
Needle /Profoject™ Tuberculin Syringe with Permanent Needle; Profoject™
Low Dead Space Safety Syringe /Profoject™ Tuberculin Safety Syringe

Regulation Number: 21 CFR 880.5860

Regulation Name: Piston Syringe

Regulatory Class: Class II

Product Code: QNQ, MEG

Dated: September 2, 2025

Received: January 20, 2026

Dear Monica Ma:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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

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

Indications for Use

510(k) Number (if known)
K252814

Device Name

Profoject™ Low Dead Space Syringe /Profoject™ Tuberculin Syringe; Profoject™ Low Dead Space Syringe with Needle /Profoject™ Tuberculin Syringe with Needle; Profoject™ Low Dead Space Syringe with Permanent Needle /Profoject™ Tuberculin Syringe with Permanent Needle; Profoject™ Low Dead Space Safety Syringe /Profoject™ Tuberculin Safety Syringe

Indications for Use (Describe)

Profoject™ Low Dead Space Syringe /Profoject™ Tuberculin Syringe is used to inject fluids into, or withdraw fluids from, the body.

Profoject™ Low Dead Space Syringe with Needle/ Profoject™ Tuberculin Syringe with Needle is used to inject fluids into, or withdraw fluids from, the body.

Profoject™ Low Dead Space Syringe with Permanent Needle /Profoject™ Tuberculin Syringe with Permanent Needle is intended for use to inject fluid into or withdraw fluids from the parts of body below the surface of the skin.

Profoject™ Low Dead Space Safety Syringe /Profoject™ Tuberculin Safety Syringe is intended for use to inject fluid into or withdraw fluids from the parts of body below the surface of the skin. The Sharps Injury Prevention Feature (SIPF) is designed to aid in the prevention of needle stick injuries and 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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K252814 510(k) Summary

[As required by 21 CFR 807.92]

1. Submission Information

510(k) Number:	K252814
Date:	February 12, 2026
Type of 510(k) Submission:	Traditional
Submitter:	CMT HEALTH PTE. LTD. 150 BEACH ROAD, #28-05, GATEWAY WEST, SINGAPORE, 189720 Contact Person: Monica Ma E-mail: ra@cmthealth.com Tel: +65 6846 1379

2. Device Description

Proprietary Name	Profoject™ Low Dead Space Syringe /Profoject™ Tuberculin Syringe, Profoject™ Low Dead Space Syringe with Needle /Profoject™ Tuberculin Syringe with Needle, Profoject™ Low Dead Space Syringe with Permanent Needle /Profoject™ Tuberculin Syringe with Permanent Needle, Profoject™ Low Dead Space Safety Syringe /Profoject™ Tuberculin Safety Syringe
Common Name	Low Dead Space Piston, Syringe, Antistick
Regulation Name	Piston syringe
Product Code	QNQ, MEG
Device Class	II
Regulation Number	21 CFR 880.5860
Review Panel	General Hospital
Indications for use	
Profoject™ Low Dead Space Syringe /Profoject™ Tuberculin Syringe	Profoject™ Low Dead Space Syringe /Profoject™ Tuberculin Syringe is used to inject fluids into, or withdraw fluids from, the body.
Profoject™ Low Dead Space Syringe with Needle/ Profoject™ Tuberculin Syringe with Needle	Profoject™ Low Dead Space Syringe with Needle/ Profoject™ Tuberculin Syringe with Needle is used to inject fluids into, or withdraw fluids from, the body.
Profoject™ Low Dead Space Syringe with Permanent Needle /Profoject™ Tuberculin Syringe with Permanent Needle	Profoject™ Low Dead Space Syringe with Permanent Needle /Profoject™ Tuberculin Syringe with Permanent Needle is intended for use to inject fluid into or withdraw fluids from the parts of body below the surface of the skin.

<p>Profoject™ Low Dead Space Safety Syringe /Profoject™ Tuberculin Safety Syringe</p>	<p>Profoject™ Low Dead Space Safety Syringe /Profoject™ Tuberculin Safety Syringe is intended for use to inject fluid into or withdraw fluids from the parts of body below the surface of the skin. The Sharps Injury Prevention Feature (SIPF) is designed to aid in the prevention of needle stick injuries and syringe reuse.</p>
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Device Description	
Profoject™ Low Dead Space Syringe /Profoject™ Tuberculin Syringe	Profoject™ Low Dead Space Syringe /Profoject™ Tuberculin Syringe consists of a barrel with a Luer Slip or Luer Lock connector which comply with ISO 80369-7, a plunger, and a plunger stopper. The device is available in 0.5 mL and 1 mL capacities. It is sterile, single-use, and non-toxic device that operates on the principle of a piston syringe.
Profoject™ Low Dead Space Syringe with Needle/ Profoject™ Tuberculin Syringe with Needle	Profoject™ Low Dead Space Syringe with Needle/ Profoject™ Tuberculin Syringe with Needle is sterile, single-use device. Each consists of either a Luer slip or Luer lock syringe assembly integrated with a pre-attached needle, and the syringe is available in two capacities (0.5mL and 1mL). For each capacity variant, the pre-attached needle is available in the following gauge specifications: 16G, 18G, 19G, 21G, 22G, 23G, 25G, 27G and 30G.
Profoject™ Low Dead Space Syringe with Permanent Needle /Profoject™ Tuberculin Syringe with Permanent Needle	Profoject™ Low Dead Space Syringe with Permanent Needle /Profoject™ Tuberculin Syringe with Permanent Needle is sterile, single-use, non-toxic devices that work on the principle of a piston syringe, and the syringes are available in three capacities: 0.3mL, 0.5mL, and 1mL. Each capacity variant is equipped with a permanently attached needle, available in the following gauge specifications: 21G, 23G, 25G, 26G, 27G, 28G, 29G, 30G and 31G.
Profoject™ Low Dead Space Safety Syringe /Profoject™ Tuberculin Safety Syringe	Profoject™ Low Dead Space Safety Syringe /Profoject™ Tuberculin Safety Syringe is sterile, single-use, non-toxic devices that work on the principle of a piston syringe, and the syringes are available in three capacities: 0.3mL, 0.5mL, and 1mL. Each capacity variant is equipped with a permanently attached needle, available in the following gauge specifications: 21G, 23G, 25G, 26G, 27G, 28G, 29G, 30G and 31G.

3. Predicate Device Identification

Profoject™ Low Dead Space Syringe /Profoject™ Tuberculin Syringe, Profoject™ Low Dead Space Syringe with Needle/ Profoject™ Tuberculin Syringe with Needle	K242291 - SOL-M Luer Lock Syringe (Low Dead Space) w/o Needle, SOL-M Slip Tip Syringe (Low Dead Space) w/o needle, SOL-M Luer Lock Syringe (Low Dead Space) w/Exchangeable Needle, SOL-CARE Luer Lock Syringe (Low Dead Space) w/Safety Needle, SOLM Slip Tip Syringe (Low Dead Space) w/Exchangeable Needle
Profoject™ Low Dead Space Syringe with Permanent Needle /Profoject™ Tuberculin Syringe with Permanent Needle	K231856 - TopFine® LDS (Low Dead Space) Syringe (2 models (TS-LDS2334, TSLDS2534))
Profoject™ Low Dead Space Safety Syringe /Profoject™ Tuberculin Safety Syringe	K231856 - TopFine® LDS (Low Dead Space) Syringe (2 models (TS-LDS2334, TSLDS2534)) Reference Device: K220204 - Safety Syringe with permanently attached needle.

4. Non-Clinical Test Conclusion

Non-clinical verification of the Profoject™ Low Dead Space Syringe /Profoject™ Tuberculin Syringe,

Profoject™ Low Dead Space Syringe with Needle/ Profoject™ Tuberculin Syringe with Needle, Profoject™ Low Dead Space Syringe with Permanent Needle /Profoject™ Tuberculin Syringe with Permanent Needle, Profoject™ Low Dead Space Safety Syringe /Profoject™ Tuberculin Safety Syringe have been conducted to evaluate their safety, performance, and functionality.

The results of these tests have demonstrated the overall performance of the proposed device in accordance with relevant test methods and support a substantial equivalence determination. Particularly, the following was conducted to adequately demonstrate the performance of the proposed device in accordance with relevant test methods cited below:

Performance Testing

1. ISO 7864 Fourth edition 2016-08-01 Sterile hypodermic needles for single use - Requirements and test methods
2. ISO 9626 Second edition 2016-08-01 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
3. ISO 7886-1 Second edition 2017-05 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
4. ISO 23908: 2011 Sharps Injury Protection – Requirements and Test Methods – Sharps Protection Features for Single Use Hypodermic Needles, Introducers for Catheters and Needles Uses for Blood Sampling
5. ISO 80369-7 Second edition 2021-05 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
6. ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
7. ASTM F1140/F1140M-13 (2020) Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
8. ASTM F88/F88M-23 Standard Test Method for Seal Strength of Flexible Barrier Materials
9. ASTM F1929-23 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
10. USP - NF <71> Sterility Tests
11. ISO 10993-7 Second edition 2008-10-15 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals[Including: Amendment 1 (2019)]
12. ISTA 3A: 2018 Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less
13. ISO 11135 Second edition 2014-07-15 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]
14. USP - NF <788> Particulate Matter in Injections
15. USP - NF <85> Bacterial Endotoxin Testing
16. ISO 11607-1 Second edition 2019-02 [Including AMD1:2023] Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including Amendment 1 (2023)]

Usability Testing

FDA guidance document *Medical Devices with Sharps Injury Prevention Features*.

Biocompatibility Testing

The biocompatibility evaluation for Profoject™ Low Dead Space Syringe /Profoject™ Tuberculin Syringe, Profoject™ Low Dead Space Syringe with Needle/ Profoject™ Tuberculin Syringe with Needle,

Profoject™ Low Dead Space Syringe with Permanent Needle /Profoject™ Tuberculin Syringe with Permanent Needle, Profoject™ Low Dead Space Safety Syringe /Profoject™ Tuberculin Safety Syringe were conducted in accordance with ISO 10993-1:2018 Biological Evaluation of Medical Devices - Part 1. Evaluation and Testing within a Risk Management Process, as recognized by FDA. The proposed devices classified as an externally communicating with limited, blood path indirect contact.

1. ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
2. ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
3. ISO 10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation
4. USP <151> Rabbit Pyrogen Study
5. ISO 10993-11 Third edition 2017-09 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
6. ISO 10993-4 Third edition 2017-04 Biological evaluation of medical devices--Part 4: Selection of tests for interactions with blood
7. ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials

5. Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data was not including in this submission

6. Substantially Equivalent Comparison Conclusion

Table 1 Profoject™ Low Dead Space Syringe /Profoject™ Tuberculin Syringe, Profoject™ Low Dead Space Syringe with Needle /Profoject™ Tuberculin Syringe with Needle

Parameters		Proposed Device	Predicate Device	Remark
1	510(k) Number	K252814	K242291	/
2	510(k) Holder	CMT HEALTH PTE. LTD.	Sol-Millennium Medical Inc.	/
3	Device name	Profoject™ Low Dead Space Syringe /Profoject™ Tuberculin Syringe, Profoject™ Low Dead Space Syringe with Needle/ Profoject™ Tuberculin Syringe with Needle	SOL-M Luer Lock Syringe (Low Dead Space) w/o Needle, SOL-M Slip Tip Syringe (Low Dead Space) w/o needle, SOL-M Luer Lock Syringe (Low Dead Space) w/Exchangeable Needle, SOL-CARE Luer Lock Syringe (Low Dead Space) w/Safety Needle, SOLM Slip Tip Syringe (Low Dead Space) w/Exchangeable Needle	/
4	Common Name	Low Dead Space Piston Syringe	Low Dead Space Piston Syringe	Same
5	Regulation Name	Piston Syringe	Piston Syringe	Same
6	Product Code	QNQ	QNQ	Same
7	Regulation Number	21 CFR 880.5860	21 CFR 880.5860	Same

8	Review Panel	General Hospital	General Hospital	Same
9	Device Class	II	II	Same
10	Indications for use	The Profoject™ Low Dead Space Syringe/ Profoject™ Tuberculin Syringe is used to inject fluids into, or withdraw fluids from, the body. The Profoject™ Low Dead Space Syringe with Needle/ Profoject™ Tuberculin Syringe with Needle is used to inject fluids into, or withdraw fluids from, the body.	The Luer Lock/Slip Tip Syringe (Low Dead Space) is to inject fluids into, or withdraw fluids from, the body. The Luer Lock/Slip Tip Syringe (Low Dead Space) with exchangeable needle is used to inject fluids into, or withdraw fluids from, the body.	Same
11	Type of use	Prescription use	Prescription use	Same
12	Syringe configuration and material	1) Plunger stopper (IR rubber) 2) Plunger (PP) 3) Barrel (PP) 4) Lubricant (polydimethylsiloxane)	1) Plunger stopper (IR rubber) 2) Plunger (PP) 3) Barrel (PP) 4) Lubricant (Silicone)	Different # 1
13	Needle material (for Profoject™ Low Dead Space Syringe with Needle/ Profoject™ Tuberculin Syringe with Needle)	SUS 304	SUS 304	Same
14	Luer lock	Luer lock or Luer slip (Slip Tip)	Luer lock or Luer slip (Slip Tip)	Same
15	Syringe volume	0.5mL, 1 mL	1 mL	Different # 2
16	Luer compliance	ISO 80369-7	ISO 80369-7	Same
17	Needle gauge and length	16G,18G,19G,20G,21G,22G,23G,25G, 26G,27G,30G 3/8", 1/2", 5/8", 3/4", 7/8", 1", 1 1/4", 1 1/2", 2"	23G, 25G, 27G, 30G 1/2", 5/8", 1", 1 1/2"	Different # 2
18	Needle performance	Conforming with ISO 9626 and ISO 7864	Conforming with ISO 9626 and ISO 7864	Same
19	Syringe performance	Conforming with ISO 7886-1	Conforming with ISO 7886-1	Same
20	Dead space specification	Syringe: Low Dead Space Max: 0.035mL	Syringe: Low Dead Space Max: 0.02mL	Different # 3
21	Biocompatibility	Conforms with ISO 10993-1	Conforms with ISO 10993-1	Same

22	Sterility	Sterile	Sterile	Same
23	Sterilization method	EO Sterilization	EO Sterilization	Same
24	Shelf Life	5 years	5 years	Same
Discussion	<p># 1 - Syringe configuration and material: The materials of lubricant are different between the proposed device and predicate device. This difference does not raise any new questions of safety and effectiveness. The biocompatibility test of the proposed device was conducted to demonstrate that the proposed device met the biocompatibility requirements.</p> <p># 2 - Syringe volume, Needle gauge and length: The syringe volume and needle gauge of the proposed device are different from those of the predicate device. However, this difference is just in dimension. Different syringe or needle specifications will be selected by physicians based on patients' conditions, and the differences does not raise new questions of safety and effectiveness. In addition, bench performance testing was conducted on the proposed device according to ISO 7886-1, ISO 7864, ISO 9626, and ISO 80369-7, and the results met the requirements of these standards. Therefore, the difference in syringe volume, needle gauge, and needle length does not raise different questions of safety and effectiveness when compared to the predicate device.</p> <p># 3 - Dead space specification: While the Low Dead Space maximum limits differ between the proposed device and predicate device, both are significantly below the ISO 7886-1 requirement of 0.07 mL for syringes ≤ 2 mL. This difference does not affect the substantial equivalence of the proposed device's Low Dead Space syringe compared to the predicate device.</p>			
Conclusion	Based on the comparison of indications for use, type of use, performance test, dead space specification, etc. the device is as safe, as effective, and performs as well as the legally marketed device identified in the submission. Thus, the proposed device is substantially equivalent to the predicate device.			

Table 2 Profoject™ Low Dead Space Syringe with Permanent Needle /Profoject™ Tuberculin Syringe with Permanent Needle

Parameters	Proposed Device	Predicate Device	Remark	
1	510(k) Number	K252814	K231856	/
2	510(k) Holder	CMT HEALTH PTE. LTD.	MedExel Co., Ltd.	/
3	Trade Name	Profoject™ Low Dead Space Syringe with Permanent Needle /Profoject™ Tuberculin Syringe with Permanent Needle	TopFine® LDS (Low Dead Space) Syringe (2 models (TS-LDS2334, TSLDS2534))	/
4	Common name	Low Dead Space Piston Syringe	Low Dead Space Piston Syringe	Same
5	Regulation Name	Piston syringe	Piston syringe	Same
6	Product Code	QNQ	QNQ	Same
7	Regulation Number	21 CFR 880.5860	21 CFR 880.5860	Same
8	Review Panel	General Hospital	General Hospital	Same
9	Device Class	II	II	Same
10	Type of use	Prescription Use	Prescription Use	
11	Indications for use	Profoject™ Low Dead Space Syringe with Permanent Needle	TopFine® LDS (Low Dead Space) Syringe is intended	Same

		/Profoject™ Tuberculin Syringe with Permanent Needle is intended for use to inject fluid into or withdraw fluids from the parts of body below the surface of the skin.	for use to inject fluid into or withdraw fluids from the parts of body below the surface of the skin.	
12	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
13	Number of uses	Single Use Only	Single Use Only	Same
14	Configuration and material	1) Barrel: Polypropylene 2) Plunger: Polypropylene 3) Plunger Stopper: Polyisoprene rubber 4) Needle: SUS 304 5) Needle Cap: High Density Polyethylene 6) Needle Hub: Polypropylene	1) Barrel: Polypropylene 2) Plunger: Polypropylene 3) Gasket: Polyisoprene rubber 4) Needle: SUS 304 5) Needle Cap: Polypropylene	Different #1
15	Needle gauge	21G, 23G, 25G, 26G, 27G, 28G, 29G, 30G, 31G	23G, 25G	Different # 2
16	Needle dimension – OD	1) 21Gauge:0.800-0.830 2) 23Gauge:0.600-0.673 3) 25Gauge:0.500-0.530 4) 26Gauge:0.440-0.470 5) 27 Gauge:0.400-0.420 6) 28 Gauge:0.349-0.370 7) 29 Gauge:0.324-0.351 8) 30 Gauge:0.298-0.320 9) 31 Gauge:0.254-0.267	23G: 0.600 ~ 0.673 mm 25G: 0.500 ~ 0.530 mm	
17	Needle dimension – needle length	13 mm(+1 / -2 mm) 10 mm(+1 / -2 mm) 8 mm(+1 / -2 mm)	26.5 mm (+1.5 / -2.5 mm)	
18	Mechanical specification	Hub/needle bond strength (ISO 7864) 1) 21Gauge:44 N 2) 23Gauge:34 N 3) 25Gauge:22 N 4) 26Gauge:22 N 5) 27 Gauge:22 N 6) 28 Gauge:22N 7) 29 Gauge:22 N 8) 30 Gauge:11 N 9) 31 Gauge:11 N	Hub/needle bond strength (ISO 7864) 1) 23 Gauge: 34 N 2) 25 Gauge: 22 N	
19	Syringe capacity	0.3mL, 0.5mL, 1mL	1mL	
20	Syringe nozzle type	Permanently attached	Permanently attached	Same

21	Dead space	Low dead volume ≤ 0.035 ml	Low dead volume ≤ 0.03 ml	Different # 3
22	Needle Performance	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
23	Syringe Performance	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
24	Sterility	Sterilized by EO Gas SAL= 10^{-6}	Sterilized by EO Gas SAL= 10^{-6}	Same
25	Endotoxin limit	20 EU/Device	20 EU/Device	Same
26	Labeling	Complies with 21 CFR part 801	Complies with 21 CFR part 801	Same
27	Biocompatibility	According to ISO 10993-1	According to ISO 10993-1	Same
Discussion	<p># 1 - Configuration and material: Compared to the predicate device, the proposed device incorporates an additional needle hub, and performance testing has demonstrated that proposed device compliant with ISO 7864 and ISO 7886-1 requirements. Through the biocompatibility test, the results confirmed that the materials of the proposed device will not cause any safety issues and effectiveness issues.</p> <p># 2 - Syringe capacity, Needle specification and Mechanical specification: The syringe capacity, needle gauge and needle length of the proposed device are different from those of the predicate device. However, this difference is limited to dimensional variations. Different syringe or needle specifications will be selected based on different clinical usages. In addition, bench performance testing was conducted on the proposed device according to ISO 7886-1, ISO 7864, ISO 9626 and ISO 80369-7, the results met the requirements of these standards. The hub/needle bond strength of proposed device are different from those of the predicate device, and bench performance testing was conducted on the proposed device according to ISO 7864, and the results met the requirements of these standards. Therefore, the difference in proposed device does not raise different questions of safety and effectiveness.</p> <p># 3 - Dead space: While the Low Dead Space maximum limits differ between the proposed device and predicate device, both are significantly below the ISO 7886-1 requirement of 0.07 mL for syringes ≤ 2 mL. This difference does not affect the substantial equivalence of the proposed device's Low Dead Space syringe compared to the predicate device.</p>			
Conclusion	Based on the comparison of indications for use, type of use, performance test, dead space specification, etc. the device is as safe, as effective, and performs as well as the legally marketed device identified in the submission. Thus, the proposed device is substantially equivalent to the predicate device.			

Table 3 Profoject™ Low Dead Space Safety Syringe /Profoject™ Tuberculin Safety Syringe

Parameters		Proposed Device	Predicate Device	Reference Device	Remark
1	510(k) Number	K252814	K231856	K220204	/
2	510(k) Holder	CMT HEALTH PTE. LTD.	MedExel Co., Ltd.	Anhui Tiankang Medical Technology Co., Ltd.	/
3	Trade Name	Profoject™ Low Dead Space Safety Syringe /Profoject™ Tuberculin Safety Syringe	TopFine® LDS (Low Dead Space) Syringe (2 models (TS-LDS2334, TSLDS2534))	Disposable Syringe with permanently attached needle, Safety Syringe with permanently attached needle	/
4	Regulation Name	Piston syringe	Piston syringe	Piston syringe	Same
5	Product Code	QNQ, MEG	QNQ	MEG	Different #1
6	Regulation Number	21 CFR 880.5860	21 CFR 880.5860	21 CFR 880.5860	Same
7	Review Panel	General Hospital	General Hospital	General Hospital	Same
8	Device Class	II	II	II	Same
9	Type of use	Prescription Use	Prescription Use	Prescription Use	Same
10	Indications for use	Profoject™ Low Dead Space Safety Syringe /Profoject™ Tuberculin Safety Syringe is intended for use to inject fluid into or withdraw fluids from the parts of body below the surface of the skin. The Sharps Injury Prevention Feature (SIPF) is designed to aid in the prevention of needle stick injuries and syringe reuse.	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.	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
11	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.	Unpublished	Different # 2

		Sharps Injury Prevention Feature is manually activated by the user by a finger-tip or thumb operation.			
12	Number of uses	Single Use Only	Single Use Only	Single Use Only	Same
13	Configuration and material	<p>1) Barrel: Polypropylene</p> <p>2) Plunger: Polypropylene</p> <p>3) Plunger stopper: Polyisoprene rubber</p> <p>4) Needle: SUS 304</p> <p>5) Needle Cap: High Density Polyethylene</p> <p>6) Collar: Polycarbonate</p> <p>7) Protective shield: Polypropylene</p>	<p>1) Barrel: Polypropylene</p> <p>2) Plunger: Polypropylene</p> <p>3) Gasket: Polyisoprene rubber</p> <p>4) Needle: SUS 304</p> <p>5) Needle Cap: Polypropylene</p>	<p>1) Barrel (PP)</p> <p>2) Plunger (PP)</p> <p>3) Piston (Polyisoprene)</p> <p>4) Needle: Stainless Steel 304)</p> <p>5) Protective cap (PP)</p> <p>6) Safety mechanism Connector base (PC)</p> <p>7) Safety mechanism Sliding sleeve (PP)</p>	Different # 3
14	Needle gauge	21G, 23G, 25G, 26G, 27G, 28G, 29G, 30G, 31G	23G, 25G	21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G, 31G	
15	Needle dimension – OD	<p>1) 21Gauge:0.800-0.830</p> <p>2) 23Gauge:0.600-0.673</p> <p>3) 25Gauge:0.500-0.530</p> <p>4) 26Gauge:0.440-0.470</p> <p>5) 27 Gauge:0.400-0.420</p> <p>6) 28 Gauge:0.349-0.370</p> <p>7) 29 Gauge:0.324-0.351</p> <p>8) 30 Gauge:0.298-0.320</p> <p>9) 31 Gauge:0.254-0.267</p>	<p>23G: 0.600 ~ 0.673 mm</p> <p>25G: 0.500 ~ 0.530 mm</p>	Unpublished	Different # 4
16	Needle dimension – needle length	<p>25 mm(+1.5 / -2.5 mm)</p> <p>20 mm(+1 / -2 mm)</p> <p>15 mm(+1 / -2 mm)</p> <p>13 mm(+1 / -2 mm)</p> <p>10 mm(+1 / -2 mm)</p> <p>8 mm(+1 / -2 mm)</p>	26.5 mm (+1.5 / -2.5 mm)	8mm, 10mm, 13mm, 16mm, 20mm, 22mm, 25mm, 32mm, 38mm	
17	Mechanical specification	Hub/needle bond strength	Hub/needle bond strength	Unpublished	

		(ISO 7864) 1) 21Gauge:44 N 2) 23Gauge:34 N 3) 25Gauge:22 N 4) 26Gauge:22 N 5) 27 Gauge:22 N 6) 28 Gauge:22N 7) 29 Gauge:22 N 8) 30 Gauge:11 N 9) 31 Gauge:11 N	(ISO 7864) 1) 23 Gauge: 34 N 2) 25 Gauge: 22 N		
18	Syringe capacity	0.3mL, 0.5mL, 1mL	0.3mL, 0.5mL, 1mL	0.3ml, 0.5ml, 1ml	
19	Syringe nozzle type	Permanently attached	Permanently attached	Unpublished	Same
20	Dead space	Low dead volume ≤ 0.035 ml	Low dead volume ≤ 0.03 ml	Unpublished	Different # 5
21	Needle Performance	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	Conforms with the requirements of ISO 7864, ISO 9626	Same
22	Syringe Performance	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	Conforms with the requirements of ISO 7886-1	Same
23	Sterility	Sterilized by EO Gas SAL=10 ⁻⁶	Sterilized by EO Gas SAL=10 ⁻⁶	Sterilized by EO Gas SAL=10 ⁻⁶	Same
24	Endotoxin limit	20 EU/Device	20 EU/Device	Unpublished	Same
25	Labeling	Complies with 21 CFR part 801	Complies with 21 CFR part 801	Complied with 21 CFR part 801	Same
26	Biocompatibility	According to ISO 10993-1	According to ISO 10993-1	Contact level: blood path, indirect, limited contact (<24 hours). Conforms to the requirement of ISO 10993 series Standards	Same
Discussion	<p># 1 - Product Code</p> <p>The proposed device is a low dead space syringe with a sharps injury prevention feature, therefore the corresponding product codes are QNQ and MEG. Proposed device, predicate device and reference device are all used by health care professionals for fluid aspiration and injection. Therefore, the difference on product code will not raise new questions of safety and effectiveness of the proposed device.</p>				

	<p># 2 - Mechanism of action</p> <p>The proposed device incorporates sharps injury prevention feature. The safety feature performance test has been evaluated, and the test result conforms to requirements of ISO 23908 standards. Therefore, the differences with predicate devices do not affect substantial equivalence.</p> <p># 3 - Configuration and material:</p> <p>The configuration and material for proposed device are different from predicate device, through the biocompatibility and performance test, the results confirmed that the configuration and materials of the proposed device do not raise any new questions of safety and effectiveness.</p> <p># 4 - Needle specification and Mechanical specification:</p> <p>The syringe volume, needle gauge and needle length of the proposed device are different from those of the predicate device. However, this difference is limited to dimensional variations. Different syringe or needle specifications will be selected based on different clinical usages. In addition, bench performance testing was conducted on the proposed device according to ISO 7886-1, ISO 7864, ISO 9626, and ISO 80369-7, and the results met the requirements of these standards.</p> <p>The hub/needle bond strength of proposed device are different from those of the predicate device. However, bench performance testing was conducted on the proposed device according to ISO 7864, and the results met the requirements of these standards. Therefore, the difference in proposed device does not raise different questions of safety and effectiveness.</p> <p># 5 - Dead Space:</p> <p>While the Low Dead Space maximum limits differ between the proposed device and predicate device, both are significantly below the ISO 7886-1 requirement of 0.07 mL for syringes ≤ 2 mL. This difference does not affect the substantial equivalence of the proposed device's Low Dead Space syringe compared to the predicate device.</p>
Conclusion	Based on the comparison of indications for use, type of use, performance test, etc. the device is as safe, as effective, and performs as well as the legally marketed device identified in the submission. Thus, the proposed device is substantially equivalent to the predicate device and reference device.

The Conclusions:

The conclusions drawn from the non-clinical tests demonstrate that the devices are as safe, as effective, and performs as well as the legally marketed devices identified in the submission. Thus, the subject devices are substantially equivalent to the predicate devices.