June 12, 2026

CMT Health PTE., Ltd.
Monica Ma
Primary Correspondent
150 Beach Rd., #28-05, Gateway W.
Singapore, 189720
Singapore

Re: K260514
Trade/Device Name: Profoject™ Safety Needle; Profoject™ Syringe with Safety Needle; Profoject™ Low Dead Space Syringe with Safety Needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, MEG, QNQ, FMI
Dated: May 19, 2026
Received: May 19, 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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

KYRAN R. GIBSON -S

for

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260514

Please provide the device trade name(s).

Profoject™ Safety Needle;
Profoject™ Syringe with Safety Needle;
Profoject™ Low Dead Space Syringe with Safety Needle

Please provide your Indications for Use below.

The Profoject™ Safety Needle is intended to be used with a Luer slip or Luer lock syringe for withdrawal and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlesticks.

The Profoject™ Syringe with Safety Needle is intended for use in the withdrawal and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlesticks.

The Profoject™ Low Dead Space Syringe with Safety Needle is intended for use in the withdrawal and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlesticks.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

1. Date of Preparation: February 14, 2026

2. Sponsor Identification

CMT HEALTH PTE. LTD.
150 BEACH ROAD, #28-05, GATEWAY WEST, SINGAPORE, 189720

Establishment Registration Number: 3036722184

Contact Person: Monica Ma
Position: Management Representative
Tel.: +65 6846 1379
Email: Ra@cmthealth.com

3. Designated Submission Correspondent

Name: Monica Ma
Email: Ra@cmthealth.com
Tel.: +65 6846 1379

4. Information of Proposed Device

Trade Name:	Profoject™ Safety Needle Profoject™ Syringe with Safety Needle Profoject™ Low Dead Space Syringe with Safety Needle
Common Name:	Antistick Needle Syringe with Antistick Needle Low Dead Space Syringe with Antistick Needle
Classification Name:	Piston Syringe Syringe Antistick
Classification:	II
Product Code:	FMF, MEG, QNQ
Regulation Number:	21 CFR 880.5860
Classification Name:	Hypodermic Single Lumen Needle

Classification:	II
Product Code:	FMI
Regulation Number:	21 CFR 880.5570

5. Identification of Predicate Device

5.1 Safety Needle and Syringe with Safety Needle

510(k) Number:	K212920
Trade Name:	Sterile Safety Syringe with Needle for Single Use (Used as predicate device) Sterile Safety Hypodermic Needle for Single Use (Used as predicate device) Sterile Auto-Disable Syringe with Needle for Single Use
Common Name:	Piston syringe and antistick needle
Classification Name:	Piston Syringe Syringe Antistick Hypodermic Single Lumen Needle
Classification:	II
Product Code:	FMF MEG FMI
Regulation Number:	21 CFR 880.5860 21 CFR 880.5570

5.2 Low Dead Space Syringe with Safety Needle

510(k) Number:	K232943
Trade Name:	Hypodermic Needle-Pro® EDGE™ Safety Device with Low Dead Space Syringe
Common Name:	Sterile Low Dead Space Piston Syringe, Needle, Hypodermic
Classification:	II
Product Code:	QNQ FMI MEG
Regulation Number:	21 CFR 880.5860 21 CFR 880.5570

6. Indications for Use Statement:

The Profoject™ Safety Needle is intended to be used with a Luer slip or Luer lock syringe for withdrawal and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental

needlesticks.

The Profoject™ Syringe with Safety Needle is intended for use in the withdrawal and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlesticks.

The Profoject™ Low Dead Space Syringe with Safety Needle is intended for use in the withdrawal and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlesticks.

7. Device Description

The Profoject™ Safety Needle is a sterile, single-use device, which consists of a needle tube, a needle hub, a needle cap, and a safety shield attached to the needle hub. The needle tube is made of stainless steel (SUS 304). The needle hub and the safety shield are made of polypropylene, and their colors comply with ISO 6009. The needle cap is also made of polypropylene and does not come into contact with the patient. This device is available in a variety of configurations, including different needle gauges, lengths, and wall thicknesses. It is compatible for use with a Luer slip or Luer lock syringe. The safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle sticks.

The Profoject™ Syringe with Safety Needle is a sterile, single-use device, which includes a Profoject™ Safety Needle and a Luer lock syringe (Model M or Model C) comprising a polypropylene barrel, a polypropylene plunger, and a polyisoprene rubber plunger stopper. This device is available in various combination of syringe volume and needle size. The syringe and the safety needle are not provided pre-assembled; instead, they are to be assembled by the user at the time of use. The needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle sticks.

The Profoject™ Low Dead Space Syringe with Safety Needle is a sterile, single-use device, which includes a Profoject™ Safety Needle and a Luer lock low dead space syringe comprising a polypropylene barrel, a polypropylene plunger, and a polyisoprene rubber plunger stopper. The proposed device offers 1mL syringes configurable with a range of needle sizes. The low dead space syringe and the safety needle are not provided pre-assembled; instead, they are to be assembled by the user at the time of use. The needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle sticks. This device is specifically designed to minimize dead space and reduce fluid waste.

The Profoject™ Safety Needle, the Profoject™ Syringe with Safety Needle and the Profoject™ Low Dead Space Syringe with Safety Needle are sterilized by ethylene oxide to achieve a Sterility Assurance Level (SAL) of 10^{-6} and are supplied in a sterility maintenance package that can maintain the sterility of the device during its 5-year shelf life.

The specifications of the proposed devices are provided in following table.

Table 1 Specifications of the Profoject™ Safety Needle

Needle Gauge	Designated Metric Size (mm)	Needle Length (mm)	Wall Thickness
18G	1.20	22, 25, 30, 38	RW, TW
19G	1.10	20, 22, 25, 30, 38	RW, TW
20G	0.90	20, 22, 25, 30, 38	RW, TW
21G	0.80	20, 22, 25, 30, 38	RW, TW
22G	0.70	13, 15, 20, 22, 25, 30, 38	RW, TW
23G	0.60	13, 15, 20, 22, 25, 30, 38	RW, TW
25G	0.50	10, 13, 15, 20, 22, 25, 30, 38	RW, TW
26G	0.45	10, 13, 15, 20, 22, 25, 30, 38	RW, TW
27G	0.40	10, 13, 15, 20, 22, 25, 30, 38	RW, TW
30G	0.30	10, 13, 15, 20, 22, 25, 30, 38	RW, TW

Table 2 Specifications of the Profoject™ Syringe with Safety Needle

Model	Syringe Volume	Needle Gauge	Connector Type	Needle Length (mm)	Wall Thickness
Model C / Model M	1mL	25G	LL	10, 13, 15, 20, 22, 25, 30, 38	RW, TW
		26G		10, 13, 15, 20, 22, 25, 30, 38	RW, TW
		27G		10, 13, 15, 20, 22, 25, 30, 38	RW, TW
		30G		10, 13, 15, 20, 22, 25, 30, 38	RW, TW
Model C / Model M	3mL	20G	LL	20, 22, 25, 30, 38	RW, TW
		21G		20, 22, 25, 30, 38	RW, TW
		22G		13, 15, 20, 22, 25, 30, 38	RW, TW
		23G		13, 15, 20, 22, 25, 30, 38	RW, TW
		25G		10, 13, 15, 20, 22, 25, 30, 38	RW, TW
Model C / Model M	5mL	20G	LL	20, 22, 25, 30, 38	RW, TW
		21G		20, 22, 25, 30, 38	RW, TW
		22G		13, 15, 20, 22, 25, 30, 38	RW, TW

		23G		13, 15, 20, 22, 25, 30, 38	RW, TW
Model C	6mL	20G	LL	20, 22, 25, 30, 38	RW, TW
		21G		20, 22, 25, 30, 38	RW, TW
		22G		13, 15, 20, 22, 25, 30, 38	RW, TW
		23G		13, 15, 20, 22, 25, 30, 38	RW, TW
Model C / Model M	10mL	20G	LL	20, 22, 25, 30, 38	RW, TW
		21G		20, 22, 25, 30, 38	RW, TW
		22G		13, 15, 20, 22, 25, 30, 38	RW, TW
		23G		13, 15, 20, 22, 25, 30, 38	RW, TW
Model C	12mL	20G	LL	20, 22, 25, 30, 38	RW, TW
		21G		20, 22, 25, 30, 38	RW, TW
		22G		13, 15, 20, 22, 25, 30, 38	RW, TW
		23G		13, 15, 20, 22, 25, 30, 38	RW, TW

Table 3 Specifications of the Profoject™ Low Dead Space Syringe with Safety Needle

Syringe Volume	Needle Gauge	Connector Type	Needle Length (mm)	Wall Thickness
1mL	25G	LL	10, 13, 15, 20, 22, 25, 30, 38	RW, TW
	26G		10, 13, 15, 20, 22, 25, 30, 38	RW, TW
	27G		10, 13, 15, 20, 22, 25, 30, 38	RW, TW
	30G		10, 13, 15, 20, 22, 25, 30, 38	RW, TW

8. Substantially Equivalent (SE) Comparison

Table 4 General Comparison of Profoject™ Safety Needle

Item	**Proposed Device**		**Predicate Device K212920**		**Comments**
Product	Profoject™ Safety Needle		Sterile Safety Hypodermic Needle for Single Use		/
Product Code	FMI		FMI		Same
Regulation No.	21 CFR 880.5570		21 CFR 880.5570		Same
Indications for Use	The Profoject™ Safety Needle is intended to be used with a Luer slip or Luer lock syringe for withdrawal and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlesticks.		The Sterile Safety Hypodermic Needle for Single Use is intended to be used with a Luer slip or Luer lock syringe for aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlesticks.		Same
Configuration	Needle hub Needle tube Needle cap Safety shield		Needle hub Needle tube Needle cap Safety shield		Same
Operation Mode	For manual use only		For manual use only		Same
Single Use	Single Use		Single Use		Same
Label/Labeling	Complied with 21 CFR part 801		Complied with 21 CFR part 801		Same
Connector Type	Luer Lock/Luer Slip		Luer Lock/Luer Slip		Same
Needle Gauge	18G, 19G, 20G, 21G, 22G, 23G, 25G, 26G, 27G, 30G		18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G		Different See comment 1
Needle Length	10mm, 13mm, 15mm, 20mm, 22mm, 25mm, 30mm, 38mm		13mm, 16mm, 19mm, 22mm, 25mm, 32mm, 38mm		Different See comment 1
Needle Hub	Color-coded per ISO 6009		Color-coded per ISO 6009		Same
Needle Performance	Complied with ISO 7864 ISO 9626 ISO 80369-7		Complied with ISO 7864 ISO 9626 ISO 80369-7		Same
Safety Mechanism	Similar safety shield and same manual activated mechanism.		Similar safety shield and same manual activated mechanism.		Same
Material	Needle hub	Polypropylene (PP)	Needle hub	Polypropylene (PP)	Same
	Needle tube	Stainless Steel	Needle tube	Stainless Steel	Same
	Safety shield	Polypropylene (PP)	Safety shield	Polypropylene (PP)	Same
	Needle cap	Polypropylene (PP)	Needle cap	Polypropylene (PP)	Same
Biocompatibility	Conforms with ISO 10993-1		Conforms with ISO 10993-1		Same
Sterilization Method	EO Sterilized		EO Sterilized		Same
SAL	10^{-6}		10^{-6}		Same

Endotoxin Limit	20 EU per device	20 EU per device	Same

Discussion:

Comment 1

The needle gauge and needle length of the proposed device are different from those of the predicate device. However, this difference is just in dimension. Different needle specifications will be selected by physicians based on patients' conditions, and this difference does not affect the intended use. In addition, bench performance testing was conducted on the proposed device according to ISO 7864, ISO 9626, and ISO 80369-7, and the results met the requirements of these standards. Therefore, the difference in needle gauge and needle length does not raise different questions of safety and effectiveness when compared to the predicate device.

Table 5 General Comparison of Profoject™ Syringe with Safety Needle

Item	**Proposed Device**		**Predicate Device K212920**		**Comments**
Product	Profoject™ Syringe with Safety Needle		Sterile Safety Syringe with Needle for Single Use		/
Product Code	FMF FMI MEG		FMF FMI MEG		Same
Regulation No.	21 CFR 880.5860 21 CFR 880.5570		21 CFR 880.5860 21 CFR 880.5570		Same
Class	Class II		Class II		Same
Indications for Use	The Profoject™ Syringe with Safety Needle is intended for use in the withdrawal and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlesticks.		The Sterile Safety Syringe with Needle for Single Use is intended for use in the aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlesticks.		Same
Configuration	Syringe	Barrel (Luer lock)	Syringe	Barrel (Luer lock/Luer slip)	Different See comment 2
		Plunger		Plunger	Same
		Plunger stopper		Plunger stopper	Same
	Needle	Needle hub	Needle	Needle hub	Same
		Needle tube		Needle tube	Same
		Needle cap		Needle cap	Same
		Safety shield		Safety shield	Same
Operation Mode	For manual use only		For manual use only		Same
Single Use	Single Use		Single Use		Same
Label/Labeling	Complied with 21 CFR part 801		Complied with 21 CFR part 801		Same
Syringe Volume	1mL, 3mL, 5mL, 6mL, 10mL, 12mL		1ml, 2ml, 2.5ml, 3ml, 5ml, 10ml, 20ml,		Different

				25ml, 30ml, 50ml, 100ml		See comment 3
Needle	Connector Type	Luer Lock		Luer Lock/Luer Slip		Different See comment 4
	Needle Gauge	20G, 21G, 22G, 23G, 25G, 26G, 27G, 30G		18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G		Different See comment 5
	Needle Length	10mm, 13mm, 15mm, 20mm, 22mm, 25mm, 30mm, 38mm		13mm, 16mm, 19mm, 22mm, 25mm, 32mm, 38mm		Different See comment 5
	Needle Hub	Color-coded per ISO 6009		Color-coded per ISO 6009		Same
Needle & Syringe Performance		Complied with ISO 7864 ISO 9626 ISO 7886-1 ISO 80369-7		Complied with ISO 7864 ISO 9626 ISO 7886-1 ISO 80369-7		Same
Material		Barrel	Polypropylene (PP)	Barrel	Polypropylene (PP)	Same
		Plunger	Polypropylene (PP)	Plunger	Polypropylene (PP)	Same
		Plunger stopper	Polyisoprene	Plunger stopper	Polyisoprene	Same
		Needle hub	Polypropylene (PP)	Needle hub	Polypropylene (PP)	Same
		Needle tube	Stainless Steel	Needle tube	Stainless Steel	Same
		Safety shield	Polypropylene (PP)	Safety shield	Polypropylene (PP)	Same
		Needle cap	Polypropylene (PP)	Needle cap	Polypropylene (PP)	Same
Biocompatibility		Conforms with ISO 10993-1		Conforms with ISO 10993-1		Same
Sterilization Method		EO Sterilized		EO Sterilized		Same
SAL		10^{-6}		10^{-6}		Same
Endotoxin Limit		20 EU per device		20 EU per device		Same

Discussion:

Comment 2

The predicate device's syringe barrel connector is available in both Luer lock and Luer slip configurations, whereas the proposed device features only the Luer lock configuration. This design difference does not affect the device's intended use. Furthermore, the Luer lock connector on the proposed device was tested per ISO 80369-7, and the results met the requirements of the standard. Therefore, the difference in syringe barrel connector design does not raise different questions of safety and effectiveness when compared to the predicate device.

Comment 3

The syringe volume of the proposed device is different from that of the predicate device. However, this difference is just in dimension. Different syringe specification will be selected by physicians based on patients' conditions, and this difference does not affect the intended use. In addition, bench performance testing was conducted on the proposed device according to ISO 7886-1 and ISO 80369-7, and the results met the requirements of these standards. Therefore, the difference in syringe volume does not raise different questions of safety and effectiveness when compared to the predicate device.

Comment 4

The predicate device's needle hub is available in both Luer lock and Luer slip connector configurations, whereas the proposed device's needle hub incorporates only the Luer lock configuration. This design difference does not affect the device's intended use. Furthermore, the Luer lock connector on the proposed device was tested per ISO 80369-7, and the results met the requirements of the standard. Therefore, the difference in needle hub connector types does not raise different questions of safety and effectiveness when compared to the predicate device.

Comment 5

The needle gauge and needle length of the proposed device are different from those of the predicate device. However, this difference is just in dimension. Different needle specifications will be selected by physicians based on patients' conditions, and this difference does not affect the intended use. In addition, bench performance testing was conducted on the proposed device according to ISO 7864, ISO 9626, and ISO 80369-7, and the results met the requirements of these standards. Therefore, the difference in needle gauge and needle length does not raise different questions of safety and effectiveness when compared to the predicate device.

Table 6 General Comparison of Profoject™ Low Dead Space Syringe with Safety Needle

Item	**Proposed Device**		**Predicate Device K232943**		**Comments**
Product	Profoject™ Low Dead Space Syringe with Safety Needle		Hypodermic Needle-Pro® EDGE™ Safety Device with Low Dead Space Syringe		/
Product Code	QNQ, FMI, MEG		QNQ, FMI, MEG		Same
Regulation No.	21 CFR 880.5860 21 CFR 880.5570		21 CFR 880.5860 21 CFR 880.5570		Same
Class	Class II		Class II		Same
Indications for Use	The Profoject™ Low Dead Space Syringe with Safety Needle is intended for use in the withdrawal and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlesticks.		This device is intended for use to inject fluids into or withdraw fluids from the body. The needle protection device covers the needle after use to help prevent needle sticks.		Different See comment 6
Configuration	Syringe	Barrel (Luer lock)	Syringe	Barrel (Luer lock)	Same
		Plunger		Plunger	Same
		Plunger stopper		Plunger stopper	Same
	Needle	Needle hub	Needle	Needle hub	Same
		Needle tube		Needle tube	Same
		Needle cap		Needle cap	Same
		Safety shield		Safety shield	Same
Operation Mode	For manual use only		For manual use only		Same

Single Use		Single Use		Single Use		Same
Syringe Volume		1mL		1mL, 3mL		Different See comment 7
Needle	Connector Type	Luer Lock		Luer Lock		Same
	Needle Gauge	25G, 26G, 27G, 30G		23G, 25G		Different See comment 8
	Needle Length	10mm, 13mm, 15mm, 20mm, 22mm, 25mm, 30mm, 38mm		16mm, 25mm, 38mm		Different See comment 8
Needle & Syringe Performance		Complied with ISO 7864 ISO 9626 ISO 7886-1 ISO 80369-7		Complied with ISO 7864 ISO 9626 ISO 7886-1 ISO 80369-7		Same
Material		Barrel	Polypropylene (PP)	Barrel	Polypropylene (PP)	Same
		Plunger	Polypropylene (PP)	Plunger	Polypropylene (PP)	Same
		Plunger stopper	Polyisoprene	Plunger stopper	IR rubber	Same
		Needle tube	Stainless Steel	Needle tube	Stainless Steel	Same
		Lubricant	Silicone	Needle hub	Silicone	Same
Dead Space Specification		Low Dead Space Maximum dead space: ≤ 0.035mL		Low Dead Space Maximum dead space: ≤ 0.015mL		Different See comment 9
Biocompatibility		Conforms with ISO 10993-1		Conforms with ISO 10993-1		Same
Sterilization Method		EO Sterilized		EO Sterilized		Same

Discussion:

Comment 6

The proposed device and the predicate device share the same core intended use: fluid withdrawal and injection, and post-use needle protection to reduce needlestick injuries. Both devices also feature a low dead space design. The minor differences in descriptive phrasing (e.g., "manually activated," "immediately after use" in the proposed device) do not alter the intended use or affect safety and effectiveness. These phrases provide additional clarity to users and are consistent with the predicate device's actual use. Therefore, the difference in descriptive phrasing does not raise different questions of safety and effectiveness when compared to the predicate device.

Comment 7

The syringe volume of the proposed device is different from that of the predicate device. However, this difference is just in dimension. Different syringe specification will be selected by physicians based on patients' conditions, and this difference does not affect the intended use. In addition, bench performance testing was conducted on the proposed device according to ISO 7886-1 and ISO 80369-7, and the results met the requirements of these standards. Therefore, the difference in syringe volume does not raise different questions of safety and effectiveness when compared to the predicate device.

Comment 8

The needle gauge and needle length of the proposed device are different from those of the predicate device. However, this difference is just in dimension. Different needle specifications will be selected by physicians based on patients' conditions, and this difference does not affect the intended use. In addition, bench performance testing was conducted on the proposed device according to ISO 7864, ISO 9626, and ISO 80369-7, and the results met the requirements of these standards. Therefore, the difference in needle gauge and needle length does not raise different questions of safety and effectiveness when compared to the predicate device.

Comment 9

While the dead space acceptance criteria for the proposed device differ from the predicate device, the proposed device fully complies with the requirement specified in ISO 7886-1 that mandates a dead space of ≤ 0.070 mL for syringes with a nominal volume (V) < 2 mL. Therefore, the difference in dead space acceptance criteria does not raise different questions of safety and effectiveness when compared to the predicate device.

9. Performance data

To establish substantial equivalence to the identified predicate device, the tests noted below were performed on the proposed device. The testing results proved that the proposed device complied with the applicable standards requirements and is substantially equivalent to the predicate device.

Biocompatibility testing

In accordance with ISO 10993-1 the proposed device is classified as an externally communicating device, in contact with "Blood path, indirect" with a contact duration of less than 24 hours. A biocompatibility evaluation for the proposed device was conducted per ISO 10993-1:2018 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process," and the FDA Guidance document (2023), "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The evaluation results indicated that proposed device's biocompatibility met the requirements in the standards.

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

Performance testing

The bench performance testing performed verified that the performance of the proposed device was substantially equivalent in terms of critical performance characteristics to the predicate device. These tests include:

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 7886-1:2017 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use

ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications

ISO 80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods

ISO 6009:2016 Hypodermic needles for single use — Colour coding for identification

ISO 23908:2024 Sharps injury protection — Sharps protection mechanisms for single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration — Requirements and test methods

Sterilization, packaging, and shelf-life testing

The sterilization process was validated in accordance with ISO 11135:2014, establishing the routine control and monitoring parameters. Simulated distribution testing and package integrity testing were conducted to demonstrate that the packaging effectively protects the product and maintains sterility. To support the claimed 5-year shelf-life, accelerated aging study was performed, followed by package integrity testing, sterility testing, and bench performance testing, confirming that the device remains functional and sterile throughout its shelf-life.

Sterilization validation	ISO 11135: 2014 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
EO and ECH residue test	ISO 10993-7:2008+AMD1:2019 Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals — AMENDMENT 1: Applicability of allowable limits for neonates and infants
Bacterial endotoxins test	USP <85> Bacterial Endotoxins Test
Package integrity testing	Seal strength ASTM F88/F88M-23 Standard Test Method for Seal Strength of Flexible Barrier Materials Dye penetration ASTM F1929-23 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration Visual inspection ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection Internal pressurization ASTM F1140/F1140M-13 (Reapproved 2020)e1 Standard Test Methods for Internal Pressurization Failure Resistance of Packages
Shelf-life evaluation	Sterility test USP <71> Sterility tests Physical, mechanical, chemical, and package tests were performed on aging samples to verify the claimed shelf-life of the device

Simulated clinical study

Beyond performance testing, a dedicated human factors study was conducted to evaluate the usability of the investigational device. In alignment with FDA's Medical Devices with Sharps Injury Prevention Features guidance, we carried out a simulated clinical use trial to examine both the usability and operational reliability of the safety needle's sharps injury prevention mechanism. Healthcare professionals assessed the safety needle's performance against predefined pass/fail criteria and provided qualitative feedback on their experience with the device's functional design. A total of 520 devices were tested, and no functional failures were identified throughout the trial.

10. Clinical Test Conclusion

Clinical studies are not required to demonstrate substantial equivalence to the predicate device.

11. Conclusion

The Profoject™ Safety Needle, Profoject™ Syringe with Safety Needle and Profoject™ Low Dead Space Syringe with Safety Needle are substantially equivalent to their predicate device. The non-clinical testing demonstrates that the devices are as safe, as effective and perform as well as the legally marketed device.