October 28, 2026

CMT Health PTE., Ltd.
Monica Ma
Official Correspondent
6001 Beach Rd., #19-13a, Golden Mile Tower
Singapore, 199589
Singapore

Re: K262242
Trade/Device Name: Profoject™ Safe Push Button Blood Collection Sets
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA, FPA
Dated: September 29, 2026
Received: September 30, 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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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,

Gang Peng for
David Wolloscheck
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.	K262242

Please provide the device trade name(s).

Profoject™ Safe Push Button Blood Collection Sets

Please provide your Indications for Use below.

The Profoject™ Safe Push Button Blood Collection Sets is a sterile, multi-sample, single-use fixed winged blood collection set intended to be used for insertion into a patient's vascular system for blood specimens. When used without the male adapter, the device allows the clinician to obtain blood sampling from the female hub with a syringe, if necessary, or can be used for short-term (up to 2 hours), single infusions with consideration given to patient size and appropriateness for the solution being infused. The device is not to be left in place and remain under the direct supervision of a clinician.
The recommended use of the device is to activate the needle safety feature prior to removal from the venipuncture site. The retraction of the intravenous (IV) end of the needle aids in the prevention of accidental needlestick injury.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☒ Neonates/Newborns (Birth to < 29 days old) ☒ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

[As required by 21 CFR 807.92]

1. Submission Information

510(k) Number:	K262242
Date:	July 1st, 2026
Type of 510(k) Submission:	Traditional
Submitter:	CMT HEALTH PTE. LTD. 6001 BEACH ROAD, #19-13A, GOLDEN MILE TOWER, SINGAPORE 199589 Contact Person: Monica Ma E-mail: ra@cmthealth.com Tel: +65 6846 1379

2. Device Description

Proprietary Name:	Profoject™ Safe Push Button Blood Collection Sets
Regulation Name:	Blood specimen collection device
Product Code:	JKA, FPA
Device Class:	II
Regulation Number:	21 CFR 862.1675
Review Panel:	Clinical Chemistry
Indications for use:	
Profoject™ Safe Push Button Blood Collection Sets	The Profoject™ Safe Push Button Blood Collection Sets is a sterile, multi-sample, single-use fixed winged blood collection set intended to be used for insertion into a patient's vascular system for blood specimens. When used without the male adapter, the device allows the clinician to obtain blood sampling from the female hub with a syringe, if necessary, or can be used for short-term (up to 2 hours), single infusions with consideration given to patient size and appropriateness for the solution being infused. The device is not to be left in place and remain under the direct supervision of a clinician. The recommended use of the device is to activate the needle safety feature prior to removal from the venipuncture site. The retraction of the intravenous (IV) end of the needle aids in the prevention of accidental needlestick injury.
Device Description:	
Profoject™ Safe Push Button Blood Collection Sets	The Profoject™ Safe Push Button Blood Collection Sets is a multiple-sample, sterile, single-use device that can be used for venipuncture to collect blood specimens and/or the short-term (up to 2 hours) intravenous administration of fluids. The Profoject™ Safe Push Blood Collection Set is available in four configurations, as listed below: • With Luer Adapter • Without Luer Adapter • With Standard Tube Holder • With Wide Tube Holder For each of the four configurations, the patient-end needle is available in gauges 20, 21, 22, 23, or 25, each with a Sharps Injury Protection

Mechanism (SIPM). The SIPM comes in two models: Model C and Model M. They are slightly different in structure but share the same working principle. When the button is depressed by the user, the spring is released, and the needle fully retracts and is enclosed and locked within the front and rear barrel which guards against accidental needlesticks during normal handling and disposal.

Furthermore, butterfly wings colors are used to distinguish different patient-end needle gauge sizes. The color coding complies with the requirements of ISO 6009.

The device offers three flexible tube lengths: 150 mm (6"), 180 mm (7"), and 310 mm (12"). The flexible tubing terminates in a female connector, which is available in two types: Female Luer Connector and Winged Female Luer Connector.

The device is sterilized by ethylene oxide gas to achieve a SAL of 10^{-6}. The validity periods of products have been verified to be 3 years.

3. Predicate Device Identification

K213718 - SOL-GUARD™ Safety Pull-Button Blood Collection Set

4. Non-Clinical Test Conclusion

Non-clinical verification of the Profoject™ Safe Push Button Blood Collection Sets has been conducted to evaluate their safety, performance, and functionality. The results of these tests have demonstrated the overall safety of the subject device and its effectiveness in accordance with relevant test methods and ultimately support a substantial equivalence determination. Particularly, the following was conducted to adequately demonstrate the effectiveness of the subject device in accordance with relevant test methods cited below:

Performance Testing

The bench performance testing performed verified that the performance of the subject 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 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 8536-4:2019 Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed
- 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
- ISO 6009:2016 Hypodermic needles for single use — Colour coding for identification
- USP <788> Particulate Matter in Injections

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 3-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.

- 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
- 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
- USP <85> Bacterial Endotoxins Test
- USP <71> Sterility Test
- ASTM F88/F88M-23 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1929-23 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F1140/F1140M-13 (Reapproved 2020)e1 Standard Test Methods for Internal Pressurization Failure Resistance of Packages

Biocompatibility Testing

The biocompatibility evaluation for the Profoject™ Safe Push Button Blood Collection Sets was 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 subject devices classified as an externally communicating with limited, blood path indirect contact.

- ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation
- ISO 10993-11 Third edition 2017-09 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-4 Third edition 2017-04 Biological evaluation of medical devices--Part 4: Selection of tests for interactions with blood
- ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials
- USP <151> Rabbit Pyrogen Study
- ASTM F2382-18 Standard Test Method for Assessment of Circulating Blood-Contacting Medical Device Materials on Partial Thromboplastin Time (PTT)
- ASTM F2888-19 Standard Practice for Platelet Leukocyte Count – An In Vitro Measure for Hemocompatibility Assessment of Cardiovascular Materials

5. Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data was not included in this submission

6. Substantially Equivalent Comparison Conclusion

Characteristic	Subject Device	Predicate Device	Comparis

				on
1	510(k) Number	K262242	K213718	--
2	510(k) Holder	CMT HEALTH PTE. LTD.	Sol-Millennium Medical, Inc.	--
3	Trade Name	Profoject™ Safe Push Button Blood Collection Sets	SOL-GUARD™ Safety Pull-Button Blood Collection Set	--
4	Product Code	JKA, FPA	JKA, FPA	Same
5	Regulation Number	21 CFR 862.1675	21 CFR 862.1675	Same
6	Review Panel	Clinical Chemistry	Clinical Chemistry	Same
7	Device Class	II	II	Same
8	Indications for Use	The Profoject™ Safe Push Button Blood Collection Sets is a sterile, multi-sample, single-use fixed winged blood collection set intended to be used for insertion into a patient's vascular system for blood specimens. When used without the male adapter, the device allows the clinician to obtain blood sampling from the female hub with a syringe, if necessary, or can be used for short-term (up to 2 hours), single infusions with consideration given to patient size and appropriateness for the solution being infused. The device is not to be left in place and remain under the direct supervision of a clinician. The recommended use of the device is to activate the needle safety feature prior to removal from the venipuncture site. The retraction of the intravenous (IV) end of the needle aids in the prevention of accidental needlestick injury.	The SOL-GUARD™ Safety Pull-Button Blood Collection Set is a sterile, multi-sample, single-use fixed winged blood collection set intended for venipuncture to obtain blood specimens from patients. When used without the male Luer adapter, the device allows the clinician to obtain blood sampling to the female hub with a syringe, if necessary, or can be used for short-term (up to 2 hours), single infusions with consideration given to patient size and appropriateness for the solution being infused. The device is not to be left in place and remain under the direct supervision of a clinician. The recommended use of the device is to activate the needle safety feature prior to removal the venipuncture site. The retraction of the intravenous (IV) end of the needle aids in the prevention of accidental needlestick injury.	Same
9	Type of Use	Prescription Use	Prescription Use	Same
10	Single Use	Yes	Yes	Same
11	Activation of Safety Mechanism	Push button	Pull button	Different, See Comment 1
12	Configuration	(1) Without Luer Adapter (2) With Luer Adapter	(1) Without attachment (2) With luer adapter	Different, See

		(3) With Standard Tube Holder (4) With Wide Tube Holder	(3) With pre-attached holder	Comment 2
13	Components	Patient-end Needle cap, Patient-end Needle, Spring, Patient-end Needle hub, Button, Front and rear barrel, Butterfly wings, Flexible Tube, Female connector, Adhesive, Luer adapter, Holder, Protective cap, Clamp (optional)	Needle, Glue, Spring, Needle hub, Sliding button, Needle protector, Wing, Housing A, Housing B, Tubing, Female luer lock connector, Luer adapter, Holder,	Different, See Comment 3
14	Needle Gauge Sizes	20 G, 21 G, 22 G, 23 G, 25 G	21 G, 23 G, 25 G	Different, See Comment 4
15	Needle Wall	Thin Wall, Extra Thin Wall	Thin Wall	
16	Needle Length	20 mm	20 mm	Same
17	Needle Point	3-bevel	3-bevel	Same
18	Tubing Length	6”, 7”, 12”	7”, 12”	Different, See Comment 5
19	Materials:			
	Patient-end Needle Cap	Low-density polyethylene (LDPE)	Low density polyethylene	Different, See Comment 6
	Patient-end Needle	Stainless steel	Stainless steel	
	Patient-end Needle Hub	Polycarbonate (PC)	Low density polyethylene	
	Spring	Stainless steel	Stainless steel	
	Button	Polycarbonate (PC)	Polycarbonate	
	Front Barrel	Polypropylene (PP)	Polycarbonate	
	Rear Barrel	Methyl methacrylate-acrylonitrile-butadiene-styrene copolymer (MABS)	Polycarbonate	
	Butterfly Wings	Low-density polyethylene (LDPE) Polyethylene (PE) Color additive	Polyvinyl chloride	
	Flexible Tube	Polyvinyl chloride (PVC)	Polyvinyl chloride	
	Female Connector	Acrylonitrile-butadiene-styrene copolymer (ABS) Polycarbonate (PC)	Polyvinyl chloride	

		White color additive		
	Adhesive	UV glue Cyclohexanone		
	Luer Adapter	Male Luer hub: Methyl methacrylate-acrylonitrile-butadiene-styrene copolymer (MABS) Polycarbonate (PC) Blue color additive Puncture needle: Stainless steel Rubber sleeve: Isoprene Rubber	Luer adapter hub: Polypropylene Needle cap: Low density polyethylene Needle: Stainless steel Rubber Sleeve: Polyisoprene Rubber	
	Holder	Polypropylene (PP) Blue color additive	Polypropylene	
	Protective Cap	Polypropylene (PP)	--	
	Clamp	High-density polyethylene (HDPE)	--	
20	Biocompatibility	Cytotoxicity Sensitization Intracutaneous Reactivity Pyrogenicity Acute Systemic toxicity Hemocompatibility	Cytotoxicity Sensitization Intracutaneous Reactivity Pyrogenicity Acute Systemic toxicity Hemocompatibility	Same
21	Sterile Method	Ethylene Oxide	Ethylene Oxide	Same
22	Sterility Assurance Level	10^{-6}	10^{-6}	Same
23	Shelf Life	3 years	3 years	Same

Comment 1:

For the subject device, to activate the safety mechanism, the button is pushed, while the predicate device requires to pull back the button. Both activate actions allow the release of the internal spring that withdraws the needle from the patient's arm into the safety tube of the blood collection device. Both bench testing (ISO 23908 performance testing) and Simulated Clinical Study demonstrated that the "Push" motion can activate the safety mechanism and provide the same protection for needlestick injury as the predicate device. This difference does not raise different questions of safety and effectiveness when compared to the predicate device.

Comment 2:

The subject device is available in 4 configurations, while the predicate device is available in 3 configurations. Both are derived from the following 3 types: Without puncture needle, With puncture needle, and With holder.

The fourth configuration of the subject device is an additional variant of the "with tube holder" type, featuring a wide-body tube holder. This wide tube holder is identical to the standard tube holder in terms of contact nature and principle of use, with the only difference being slight variations in dimensions. Therefore, this difference does not raise different questions of safety and effectiveness when compared to the predicate device.

Comment 3:

The subject device has two components more than the predicate device: protective cap and an optional

clamp. The protective cap is used to protect the female connector when the subject device is provided without luer adapter. The optional clamp is used prevent the liquid flow. This difference does not raise different questions of safety and effectiveness when compared to the predicate device.

Comment 4:

The needle specifications (including needle gauges and wall types) are different between the subject device and predicate device. The subject device has expanded of needle specifications. These extended specifications have been verified according to ISO 9626, ISO 7864. This difference does not raise different questions of safety and effectiveness when compared to the predicate device.

Comment 5:

The tubing length is different between the subject device and predicate device. The subject device has expanded of tubing length. These extended lengths have been verified according to ISO 8536-4. This difference does not raise different questions of safety and effectiveness when compared to the predicate device.

Comment 6:

The materials for the subject device are different from predicate device. According to guidance, Use of International Standard ISO 10993-1 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", the subject device is external communicating device of Blood path, indirect and limited contact. The biocompatibility test has been performed. The test results showed that this difference does not raise different questions of safety and effectiveness when compared to the predicate device.

7. Conclusion:

The non-clinical testing supports the determination of substantial equivalence of the subject device. Changes made to the subject device do not raise any new questions of safety or effectiveness. The Profoject™ Safe Push Button Blood Collection Sets is substantially equivalent to its predicate device (K213718).