



September 25, 2026

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

Re: K262215

Trade/Device Name: Profoject™ Safety Sliding Blood Collection Set
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA, FPA
Dated: June 30, 2026
Received: June 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.

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-S

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

510(k) Number (if known)

K262215

Device Name

Profoject™ Safety Sliding Blood Collection Set

Indications for Use (Describe)

The Profoject™ Safety Sliding Blood Collection Set is a single-use, sterile, winged blood collection needle to be used for blood collection or short-term infusion (up to 2 hours) of intravenous fluids. The device is designed with a safety mechanism to help reduce the risk of needlestick injury.

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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510(k) Summary – K262215

1. Date of Preparation: September 24, 2026

2. Sponsor Identification

CMT HEALTH PTE. LTD.

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Establishment Registration Number: 3036722184

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3. Designated Submission Correspondent

Name: Monica Ma

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Tel.: +65 6846 1379

4. Subject Device

Trade Name: Profoject™ Safety Sliding Blood Collection Set

Common Name: Safety Blood Collection Set

Device Class: Class II

Product Code: JKA

Regulation Name: Blood specimen collection device;

Regulation Number: 21 CFR 862.1675;

Review Panel: Clinical Chemistry;

Product Code: FPA

Regulation Name: Intravascular administration set;

Regulation Number: 21 CFR 880.5440;

Review Panel: General Hospital;

5. Identification of Predicate Device

510(k) Number: K163073

Trade Name: Sol-Care Safety Blood Collection Needle (with and without Pre-attached Tube Holder)

Common Name: Winged Collection Set, Small Vein Set

Regulation Number: 21 CFR 862.1675

Regulation Name: Blood specimen collection device

Regulatory Class: Class II

Product Code: JKA, FPA

Review Panel: Clinical Chemistry

6. Indications for Use Statement:

The Profoject™ Safety Sliding Blood Collection Set is a single-use, sterile, winged blood collection needle to be used for blood collection or short-term infusion (up to 2 hours) of intravenous fluids. The device is designed with a safety mechanism to help reduce the risk of needlestick injury.

7. Device Description

The Profoject™ Safety Sliding Blood Collection Set is a single-use, sterile, winged needle assembly bonded to flexible tube. It is available with or without a Luer adapter; models with a Luer adapter are offered with or without a holder, and all configurations incorporate a safety shield. The device is designed with an active safety shield that allows for immediate activation to fully cover the blood collection needle after use, protecting against accidental needlestick injuries.

Components of the Profoject™ Safety Sliding Blood Collection Set include: (1) Blood collection needle cap, (2) Butterfly wings, (3) Safety shield, (4) Blood collection needle tube, (5) Flexible tube, (6) Female Luer adapter, (7) Male Luer hub, (8) Puncture needle tube, (9) Rubber sleeve, (10) Puncture needle protective cover, (11) Holder, (12) Protective cap.

The Profoject™ Safety Sliding Blood Collection Set is available in six configurations, as listed below:

- a. With Luer adapter
- b. With standard tube holder
- c. With Luer lock access holder
- d. With wide neck access holder
- e. With wide tube holder
- f. Without Luer adapter

For each of the six models, two safety shield options are available—Shield A and Shield B. They are slightly different in structure but share the same operation principle.

Two types of female Luer adapter are also offered: female Luer connector and winged female Luer connector.

Regarding the male Luer hub:

Model a is available in both Luer lock and Luer slip versions.

Models b and e are available in both Luer lock and Luer slip versions, and the male Luer hub is detachable from the holder.

Models c and d are Luer lock only, with the hub permanently integrated into the holder as a single, non-separable unit.

Each model includes all components (1) through (6) listed above. The differences among the six models lie in which of components (7) through (12) are incorporated. The device is offered with a variety of needle gauges and flexible tube lengths.

Blood collection needles are available in 20G, 21G, 22G, 23G, and 25G, all with a needle length of 3/4" (20 mm), in both thin-walled and extra-thin-walled configurations.

Puncture needles are available in 20G (Models c and d) and 21G (Models a, b, e), with regular wall and thin wall, and in lengths of 15 mm (Models a, b, c, e) and 17 mm (Model d).

Three flexible tube length options are provided: 6" (150 mm), 7" (180 mm), and 12" (310 mm).

Butterfly wings colors are used to distinguish different needle gauge sizes. The color coding complies with the requirements of ISO 6009.

The device is intended for single use only. It is supplied sterile, sterilized by ethylene oxide (EO) with a sterilization assurance level (SAL) of 10^{-6} .

The specifications of the device are as follow:

Table 7.1 Specifications of blood collection needles and flexible tube

No.	Model	Blood collection needle gauge	Designated metric size (mm)	Needle length (mm)	Wall thickness	Flexible tube length
1	All models	20G	0.9	20 mm (3/4")	TW/ETW	150 mm (6"), 180 mm (7"), 310 mm (12")
2	All models	21G	0.8	20 mm (3/4")		
3	All models	22G	0.7	20 mm (3/4")		
4	All models	23G	0.6	20 mm (3/4")		
5	All models	25G	0.5	20 mm (3/4")		
Note: TW = Thin Wall, ETW = Extra Thin Wall						

Table 7.2 Specifications of puncture needle

No.	Model	Puncture needle gauge	Designated metric size (mm)	Needle length (mm)	Wall thickness
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1	With Luer adapter	21G	0.8	15	RW/TW
2	With standard tube holder	21G	0.8	15	RW/TW
3	With wide tube holder	21G	0.8	15	RW/TW
4	With Luer lock access holder	20G	0.9	15	RW/TW
5	With wide neck access holder	20G	0.9	17	RW/TW
Note: RW = Regular Wall, TW = Thin Wall					

8. Substantially Equivalent (SE) Comparison

Table 8.1 Comparison of Technology Characteristics

Device Feature	Proposed Device	Predicate Device K163073	Comments
Indications for use	The Profoject™ Safety Sliding Blood Collection Set is a single-use, sterile, winged blood collection needle to be used for blood collection or short-term infusion (up to 2 hours) of intravenous fluids. The device is designed with a safety mechanism to help reduce the risk of needlestick injury.	The Sol-Care Safety Blood Collection Needle (with and without Pre-attached Tube Holder) is a single-use, sterile, winged blood collection needle to be used for blood collection or short-term infusion (up to 2 hours) of intravenous fluids. The device is designed with a safety mechanism to help reduce the risk of needlestick injury.	Same
Intended use	The Profoject™ Safety Sliding Blood Collection Set is a single-use, sterile, winged blood collection needle to be used for blood collection or short-term infusion (up to 2 hours) of intravenous fluids. The device is designed with a safety mechanism to help reduce the risk of needlestick injury.	Blood Collection and Infusion of Intravenous Solutions for up to 2 Hours.	Same

Materials	Blood collection needle cap: Low-density polyethylene (LDPE) Butterfly wings: PVC Safety shield: PP Flexible tube: PVC Female Luer adapter: ABS, PC Male Luer adapter: MABS, PC Blood collection needle tube: Stainless steel SUS304 Puncture needle protective cover: PP	Blood collection needle cap: LDPE Butterfly wings: PVC Safety Shield: PP Flexible tube: PVC Female Luer: ABS Male Luer: White PP Blood collection needle tube: Stainless steel (SUS 304) Puncture needle protect cover: Clear LDPE	Different See comment 1
Configuration	With Luer adapter; With standard tube holder; With Luer lock access holder; With wide neck access holder; With wide tube holder; Without Luer adapter	With blood collection tube holder; With blood culture holder; Without pre-attached tube holder	Different See comment 2
Single-use	Yes	Yes	Same
Blood collection needle gauge	20G, 21G, 22G, 23G and 25G	21G, 23G and 25G	Different See comment 2
Blood collection needle length	3/4" (20mm)	3/4"	Same
Flexible tube length	6"(150mm), 7"(180mm) and 12"(310mm)	7"and 12"	Different See comment 2
Packaging type	Blister Pack, Pouch Pack	Tray Pack	Different See comment 3
Method of safety shield activation	One-hand activation: Hold the tubing, advance the translucent yellow safety shield with thumb and index finger until a "click" is heard or felt, indicating the safety shield is locked over the needle tip. Two-hand activation: Hold the translucent yellow safety shield with one hand, pull back the tubing with the other hand until a "click" is heard or felt, indicating the safety shield is locked over the needle tip.	After use, the health care professional can pull back on the tubing while holding the butterfly wing and the needle will retract and lock into the Safety Shield. In the activated position the needle cover guards against accidental needlesticks during normal handling and disposal.	Different See comment 4

	Optional two-hand activation: Hold one wing with one hand, grasp the yellow safety shield with the other, and advance it until a “click” is heard or felt, indicating the safety shield is locked over the needle tip.		
Sterility	Sterile	Sterile	Same
Method of sterilization	EO	EO	Same
Shelf life	3 years	3 years	Same
Performance specifications	Complies with: ISO 7864:2016 Sterile hypodermic needles for single use - 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 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 8536-4:2019 Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods	Complies with: ISO 7864:1993 Sterile hypodermic needles for single use ISO 594-2:1998 Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment Part 2: Lock fittings ISO 23908:2011 Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling ISO 8536-4:2010 Infusion equipment for medical use Part 4: Infusion sets for single use, gravity feed	Different See comment 5
Biocompatibility	The biocompatibility evaluation	The biocompatibility evaluation for	Different

	for the proposed device was conducted in accordance with the ISO 10993-1:2018 “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process”, and 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 following biocompatibility evaluation were conducted: Cytotoxicity; Intracutaneous reactivity; Skin sensitization; Acute systemic toxicity; Pyrogenicity; Hemolysis; Complement Activation; Partial Thromboplastin Time (PTT); Heparinized Blood Platelet and Leukocyte Count Assay. The evaluation of the above testing items meets the requirements.	the proposed device was conducted in accordance with the ISO 10993-1:2006, Biological evaluation of medical devices Part 1: Evaluation and testing. The following biocompatibility tests and evaluation were conducted: Cytotoxicity; Intracutaneous reactivity; Skin sensitization; Acute systemic toxicity; Hemolysis; Complement Activation; Thrombosis Testing;	See comment 6
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Discussion:

Comment 1

The materials of the proposed device differ from those of the predicate device. Per the guidance outlined in International Standard ISO 10993-1 "Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process", the proposed device is an external communicating device that interfaces with the blood path, involving indirect and limited patient contact. Relevant biological evaluations have been completed for the materials intended for human contact of the proposed device. Therefore, this material difference does not raise different questions of safety and effectiveness.

Comment 2

The configuration, needle gauge and flexible tube lengths of the proposed device differ from those of the predicate device — the proposed device has expanded the range of available needle gauges, configuration and flexible tube lengths. These expanded product variants have been verified in compliance with ISO 9626, ISO

7864, ISO80369-7 and ISO 8536-4. Therefore, this difference does not raise different questions of safety and effectiveness

Comment 3.

The primary packaging of the proposed device differs from that of the predicate device. However, both types of primary packaging serve the same functions: maintaining sterility and protecting the product. Furthermore, the proposed device's packaging has undergone package integrity testing and sterility testing, and the results met the requirements. Therefore, the difference in the form of the primary packaging does not raise different questions of safety and effectiveness.

Comment 4

The three activation methods of the proposed device share identical activation principles with the predicate device. All three activation methods were validated in simulated clinical study, demonstrating that each of the three methods can successfully trigger the safety mechanism and fulfill the intended use of the device. Thus, the difference in the activation method does not raise different questions of safety and effectiveness.

Comment 5

The proposed device has performed comprehensive needle tube performance testing in full compliance with ISO 9626. In addition, the proposed device and predicate device adopt different editions of the referenced ISO standards for performance verification; all cited standards are FDA-recognized consensus standards, and all test results of the proposed device meet the respective standard requirements. Therefore, these differences in performance specification compliance does not raise different questions of safety and effectiveness.

Comment 6

The proposed device's biocompatibility evaluation follows ISO 10993-1:2018 plus relevant 2023 FDA guidance, while the predicate device adopted the older ISO 10993-1:2006 standard. The proposed device covers a broader scope of biocompatibility test items compared to the predicate. Both ISO editions are FDA-recognized consensus standards, and all biocompatibility test results of the proposed device fully meet applicable standard criteria. Therefore, these differences in standard edition and test panel do not raise different questions of safety and effectiveness.

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.

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 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

Biocompatibility

Biocompatibility testing was conducted based upon ISO 10993-1:2018 “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,” and 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 proposed device is an externally communicating device in contact with “blood path, indirect” for less than 24 hours and the following tests and evaluation were conducted in accordance with the relevant ISO 10993 standards:

- Cytotoxicity (ISO 10993-5)
- Skin Sensitization (ISO 10993-10)
- Intracutaneous Reactivity (ISO 10993-23)
- Acute Systemic Toxicity (ISO 10993-11)
- Pyrogen (ISO 10993-11 & USP <151>)
- Hemolysis (ISO 10993-4 & ASTM F756-17)
- Complement Activation (ISO 10993-4)
- Partial Thromboplastin Time (PTT) (ISO 10993-4 & ASTM F2382-18)
- Heparinized Blood Platelet and Leukocyte Count Assay (ISO 10993-4 & ASTM F2888-19)

The test and evaluation results indicated that the 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.

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.

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 Sterility test USP <71>
Shelf-life evaluation	Physical, mechanical, chemical, and package tests were performed on aged samples to verify the claimed shelf-life of the device

Simulated clinical study

Beside performance testing, a simulated clinical study was conducted to evaluate the proposed device. In alignment with FDA's guidance on Medical Devices with Sharps Injury Prevention Features, the trial examined the usability and operational reliability of the safety mechanism. Participating medical professionals assessed the device under multiple conditions. A total of 600 devices were tested, and no functional failures were identified throughout the trial. It is concluded that the safety mechanism satisfies both usability and safety requirements for its intended use.

10. Clinical Test Conclusion

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

11. 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™ Safety Sliding Blood Collection Set is substantially equivalent to its predicate device.