October 16, 2025

CMT HEALTH PTE. Ltd.
Monica Ma
Management Representative
150 Beach Road, #28-05
Gateway West, 189720
Singapore

Re: K252631
Trade/Device Name: Profoject™ Disposable Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: Class II
Product Code: FMI
Dated: August 20, 2025
Received: August 20, 2025

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252631

Device Name
Profoject™ Disposable Needle

Indications for Use *(Describe)*
The Profoject™ Disposable Needle is intended to be used with a Luer lock or Luer slip syringe and injection devices for general purpose fluid injection/aspiration.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1. Date of Preparation: October 03, 2025

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 of Device: Profoject™ Disposable Needle
Common Name: Hypodermic Single Lumen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Review Panel: General Hospital

5. Identification of Predicate Device

Predicate Device
510(k) Number: K211214
Trade Name of Device: Sterile Hypodermic Needles for Single Use
Common Name: Hypodermic Single Lumen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI

Review Panel: General Hospital

6. Indications for Use Statement:
The Profoject™ Disposable Needle is intended to be used with a Luer lock or Luer slip syringe and injection devices for general purpose fluid injection/aspiration.

7. Device Description
The proposed device, Profoject™ Disposable Needle, consists of a needle tube, a needle hub, and a needle cap. The needle tube is made of stainless steel (SUS 304). The needle hub is made of polypropylene, and its color complies with ISO 6009. The needle cap is also made of polypropylene and does not come into contact with the patient. The conical socket of the needle hub is a Luer connector, compatible with other medical devices featuring Luer connectors. The proposed device is available in a variety of configurations, including different needle gauges, lengths, and wall thicknesses. The proposed 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 proposed device are provided in following table.

Table 1 Specifications of the Profoject™ Disposable Needle

Needle Gauge	Needle Length	Wall Thickness
16G	25mm, 30mm, 38mm, 50mm	RW
18G	22mm, 25mm, 30mm, 38mm, 50mm	RW
18G	22mm, 25mm, 30mm, 38mm	TW
19G	20mm, 22mm, 25mm, 30mm, 38mm, 50mm	RW
19G	20mm, 22mm, 25mm, 30mm, 38mm	TW
20G	20mm, 22mm, 25mm, 30mm, 38mm, 50mm	RW
20G	20mm, 22mm, 25mm, 30mm, 38mm	TW
21G	20mm, 22mm, 25mm, 30 mm, 38mm, 50mm	RW
21G	20mm, 22mm, 25mm, 30mm, 38mm	TW
22G	13mm, 15mm, 20mm, 22mm, 25mm, 30mm, 38mm	RW
22G	13mm, 15mm, 20mm, 22mm, 25mm, 30mm, 38mm	TW
23G	13mm, 15mm, 20mm, 22mm, 25mm, 30mm, 38mm	RW
23G	13mm, 15mm, 20mm, 22mm, 25mm, 30mm, 38mm	TW
25G	10mm, 13mm, 15mm, 20mm, 22mm, 25mm, 30mm, 38mm	RW
25G	10mm, 13mm, 15mm, 20mm, 22mm, 25mm, 30mm, 38mm	TW
26G	10mm, 13mm, 15mm, 20mm, 22mm, 25mm, 30mm, 38mm	RW
26G	10mm, 13mm, 15mm, 20mm, 22mm, 25mm, 30mm, 38mm	TW
27G	10mm, 13mm, 15mm, 20mm, 22mm, 25mm, 30mm, 38mm	RW
27G	10mm, 13mm, 15mm, 20mm, 22mm, 25mm, 30mm, 38mm	TW
30G	10mm, 13mm, 15mm, 20mm, 22mm, 25mm, 30mm, 38mm	RW
30G	10mm, 13mm, 15mm, 20mm, 22mm, 25mm, 30mm, 38mm	TW

8. Substantially Equivalent (SE) Comparison

Table 2 Comparison of Technology Characteristics

Device feature	Proposed Device K252631		Predicate Device K211214		Comment
Indications for use	The Profoject™ Disposable Needle is intended to be used with a Luer lock or Luer slip syringe and injection devices for general purpose fluid injection/aspiration.		The Sterile Hypodermic Needles for Single Use are intended to be used with a luer lock or luer slip syringe and injection devices for general purpose fluid injection/aspiration.		Same
Product code	FMI		FMI		Same
Regulation number	21 CFR 880.5570		21 CFR 880.5570		Same
Class	II		II		Same
Principle of operation	For manual use only		For manual use only		Same
Intended user	Medical professionals and trained care givers		Medical professionals and trained care givers		Same
Environment of use	Hospitals and clinics		Hospitals and clinics		Same
Needle gauge	30G, 27G, 26G, 25G, 23G, 22G, 21G, 20G, 19G, 18G, 16G		30G, 27G, 26G, 25G, 24G, 23G, 22G, 21G, 20G, 19G, 18G		Different See comment 1
Needle length	3/8" (10mm), 1/2" (13mm), 5/8" (15mm), 3/4" (20mm), 7/8" (22mm), 1" (25mm), 1-1/4" (30mm), 1-1/2" (38mm), 2" (50mm)		1/2", 5/8", 1", 1 1/4", 1 1/2"		Different See comment 1
Type of wall	Normal wall or thin wall		Normal wall or thin wall		Same
Main structure and materials	Needle hub	Polypropylene	Needle hub	Polypropylene	Same
	Needle tube	Stainless steel	Needle tube	Stainless steel	
	Needle cap	Polypropylene	Protective cover	Polypropylene	
Needle hub Color	Color-coded per ISO 6009		Color-coded per ISO 6009		Same
Single use	Yes		Yes		Same
Performance specifications	Complies with: ISO 7864:2016 Sterile hypodermic needles for single use - Requirements and test methods ISO 9626:2016 Stainless steel needle tubing for the		Complies with: ISO 7864:2016 Sterile hypodermic needles for single use - Requirements and test methods ISO 9626:2016 Stainless steel needle tubing for the		Same

	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 6009:2016 Hypodermic needles for single use - Colour coding for identification USP <788> Particulate Matter in Injections	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 6009:2016 Hypodermic needles for single use - Colour coding for identification USP <788> Particulate Matter in Injections	
Sterilization	EO	EO	Same
SAL	10^{-6}	10^{-6}	Same
Pyrogen	Non-pyrogenic	Non-pyrogenic	Same
Biocompatibility	The biocompatibility evaluation 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 tests were conducted: Cytotoxicity; Intracutaneous reactivity; Skin sensitization; Acute systemic toxicity;	The biocompatibility evaluation for the proposed device was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA and the "Use of International Standard ISO 10993-1 "Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process", June 16, 2016. The testing included the following tests: Cytotoxicity; Skin sensitization; Hemolysis;	Different See comment 2

	Pyrogenicity; Hemolysis; Complement Activation; Partial Thromboplastin Time (PTT). The evaluation of the above testing items meets the requirements.	Intracutaneous reactivity; Acute systemic toxicity; Pyrogenicity. The evaluation of the above testing items meets the requirements.	
Labeling	Meets the requirements of 21 CFR Part 801	Meets the requirements of 21 CFR Part 801	Same

Discussion:

Comment 1

The needle gauge and needle length of the proposed device differ 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 in accordance with ISO 7864, ISO 9626, and ISO 80369-7 was conducted on the proposed device, and the results met the requirements of the 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 2

The proposed device underwent additional biocompatibility tests compared to the predicate device, with all results meeting standards. Therefore, the difference in biocompatibility test types 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

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 were conducted in accordance with the relevant ISO 10993 standards:

- Cytotoxicity
- Skin Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity

- Pyrogen
- Hemolysis
- Complement Activation
- Partial Thromboplastin Time (PTT)

The test 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.

Performance testing

Bench performance tests were performed and the test results demonstrated that the proposed device complied with the following standards:

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

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
EO and ECH residue test	ISO 10993-7:2008+AMD1:2019
Bacterial endotoxins test	USP <85>
Package integrity testing	Seal strength ASTM F88/F88M-23
	Dye penetration ASTM F1929-23
	Visual inspection ASTM F1886/F1886M-16
	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 aging samples to verify the claimed shelf-life of the device

10. Clinical Test Conclusion

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

11. Conclusion

The Profoject™ Disposable Needle is substantially equivalent to its predicate device. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed predicate device.