July 25, 2025

CMT Health Pte. Ltd.
℅ Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K252033
Trade/Device Name: Profoject™ Disposable Syringe, Profoject™ Disposable Syringe with Needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: FMF
Dated: June 28, 2025
Received: June 30, 2025

Dear Dave Yungvirt:

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)*
K252033

Device Name
ProfojectTM Disposable Syringe, ProfojectTM Disposable Syringe with Needle

Indications for Use *(Describe)*
The ProfojectTM Disposable Syringe and the ProfojectTM Disposable Syringe with Needle are intended to be used for medical purposes to inject fluid into or withdraw fluid from body.

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."

K252033 510(k) Summary

1. Date of Preparation: May 22, 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: Profoject™ Disposable Syringe, Profoject™ Disposable Syringe with Needle
Common Name: Piston Syringe
Regulation Name: Piston syringe
Device Class: Class II
Product Code: FMF
Regulation Number: 21 CFR 880.5860
Review Panel: General Hospital

5. Identification of Predicate Device

Predicate Device
510(k) Number: K211211
Trade Name: Sterile syringes for single use with/without needle
Common Name: Piston Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF

Review Panel: General Hospital

6. Indications for Use Statement:
The Profoject™ Disposable Syringe and the Profoject™ Disposable Syringe with Needle are intended to be used for medical purposes to inject fluid into or withdraw fluid from body.

7. Device Description

The Profoject™ Disposable Syringe is available in a sterile state. It is a single-use device comprising a polypropylene barrel with a Luer slip or Luer lock nozzle, a polypropylene plunger, and a polyisoprene rubber plunger stopper. Syringes are available in various volume specifications, ranging from 1mL to 60mL. The syringe barrel is printed with a legible graduated scale in milliliters. The syringe is compatible with U.S. legally marketed devices featuring Luer slip or Luer lock connectors that comply with ISO 80369-7. The syringe is intended for manual use only. The plunger of the syringe is pulled back to aspirate fluids or depressed to inject or expel fluids.

The Profoject™ Disposable Syringe with Needle is supplied in a sterile state. It is a single-use device comprising a Luer slip or Luer lock syringe and a hypodermic needle. The hypodermic needle consists of a stainless steel needle tube, a polypropylene needle hub, and a polypropylene needle cap. The hypodermic needle is available in variety of combinations of needle gauge (18G, 20G, 21G, 22G, 23G, 25G, 26G, 27G) and needle length (15mm, 20mm, 25mm, 30mm, 38mm). Needle hubs are color-coded to identify the gauge of the needle tube. The Disposable Syringe with Needle is available in various combinations of syringe volume and needle size. It is intended for manual use only. The plunger of the syringe is pulled back to aspirate fluids or depressed to inject or expel fluids.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Device Feature	**Proposed Device**	**Predicate Device K211211**	**Comments**
Indications for use	The Profoject™ Disposable Syringe and the Profoject™ Disposable Syringe with Needle are intended to be used for medical purposes to inject fluid into or withdraw fluid from body.	The Sterile Syringes for Single Use with/without Needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.	Same
Product code	FMF	FMF	Same
Regulation number	21 CFR 880.5860	21 CFR 880.5860	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

Nozzle type	Luer slip; Luer lock	Luer slip; Luer lock	Same
Lubricant for barrel	Silicone oil	Silicone oil	Same
Barrel transparency	Transparent and clear	Transparent and clear	Same
Gradations legibility	Legible	Legible	Same
Syringe volume	1ml, 3ml, 5ml, 6ml, 10ml, 12ml, 20ml, 30ml, 35ml, 50ml, 60ml	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml, 100ml	Different See comment 1
Needle gauge	18G, 20G, 21G, 22G, 23G, 25G, 26G, 27G	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 30G	Different See comment 1
Needle length	15mm (5/8"), 20mm (3/4"), 25mm (1"), 30mm (1-1/4"), 38mm (1-1/2")	1/2", 5/8", 1", 1-1/4", 1-1/2"	Different See comment 1
Needle hub	Color-coded per ISO 6009	Color-coded per ISO 6009	Same
Single use	Yes	Yes	Same
Performance specifications	ISO 7886-1:2018 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use ISO 80369-7:2016 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 USP <788> Particulate Matter Injections ISO 7864: 2016 - Sterile hypodermic needles for single use -- Requirements and test methods ISO 6009:2016 - Hypodermic needles for single use —	ISO 7886-1:2018 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use ISO 80369-7:2016 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 USP <788> Particulate Matter Injections ISO 7864: 2016 - Sterile hypodermic needles for single use -- Requirements and test methods ISO 6009:2016 - Hypodermic needles for single use —	Same

	Colour coding for identification ISO 9626:2016 - Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods	Colour coding for identification ISO 9626:2016 - Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods	
Sterility	Sterile	Sterile	Same
Sterilization method	EO	EO	Same
SAL	10^{-6}	10^{-6}	Same
Materials	Barrel: Polypropylene (PP) Plunger: Polypropylene (PP) Plunger stopper: Polyisoprene rubber Needle tube: Stainless steel SUS304 Needle hub: Polypropylene (PP)	Barrel: PP Plunger: PP Piston: Silicone Rubber Needle: Stainless 304 Needle hub: PP	Different See comment 2
Pyrogen	Non-pyrogenic	Non-pyrogenic	Same
Biocompatibility	The biocompatibility evaluation for the proposed device was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA and the "Use of International Standard ISO 10993-1, "Biological	The biocompatibility evaluation for the subject device was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA and the "Use of International Standard ISO 10993-1 "Biological	Different See comment 3

	evaluation of medical devices-Part 1: Evaluation and testing within a risk management process", September 8, 2023. The biocompatibility testing of the proposed device included the following tests: Cytotoxicity; Skin sensitization; Intracutaneous reactivity; Acute systemic toxicity; Pyrogenicity; Hemocompatibility (Hemolysis, Complement Activation, PTT). The evaluation of the above testing items meets the requirements.	evaluation of medical devices-Part 1: Evaluation and testing within a risk management process", June 16, 2016. The syringe of testing included the following tests: Cytotoxicity; Skin sensitization; Hemolysis; Intracutaneous reactivity; Acute systemic toxicity; Pyrogenicity. The evaluation of the above testing items meets the requirements.	
Labeling	Meet the requirements of 21 CFR Part 801	Meet the requirements of 21 CFR Part 801	Same

Discussion:

Comment 1

The syringe volume, 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 syringe or 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 7886-1, ISO 7864, ISO 9626, and ISO 80369-7, and the results met the requirements of these standards. Therefore, the difference in syringe volume, needle gauge, and needle length does not raise different questions of safety and effectiveness.

Comment 2

There are differences between the materials of the proposed device and those of the predicate device. However, the proposed devices were tested, and the results demonstrated that they complied with the ISO 10993 series standards. In addition, bench performance testing in accordance with ISO 7886-1, ISO 7864, ISO 9626, and ISO 80369-7 was conducted on the proposed device, and the results met the requirements in the standards. Therefore, the difference in material does not raise different questions of safety and effectiveness.

Comment 3

The proposed device underwent additional biocompatibility testing compared to the predicate device, and all test results met the requirements of the standards. Therefore, the difference in biocompatibility test types does not raise different questions of safety and effectiveness.

9. Performance data

To establish substantial equivalence to the identified predicate device, the following tests have been performed. The testing results demonstrate that the proposed device complies with the applicable standards requirements and is substantially equivalent to the predicate device.

Biocompatibility testing

Biocompatibility of the Profoject™ Disposable Syringe and the Profoject™ Disposable Syringe with Needle were evaluated in accordance with ISO 10993-1:2018 for the body contact category of "External communication device - Blood path, indirect" with a contact duration of "Limited (≤ 24 hours)". Cytotoxicity test, skin sensitization test, intracutaneous reactivity test, acute systemic toxicity test, pyrogen test, and hemocompatibility test were conducted on the Profoject™ Disposable Syringe and the Profoject™ Disposable Syringe with Needle. The test results indicated that the devices' 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:

Standard	Title of standard
ISO 7886-1:2017	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
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 7864: 2016	Sterile hypodermic needles for single use -- Requirements and test methods
ISO 6009:2016	Hypodermic needles for single use — Colour coding for identification

Sterilization, package, and shelf life testing

- The sterilization method was validated according to ISO 11135:2014, establishing the routine control and

monitoring parameters.

The testing was performed according to the following standards:

Test item	Complied standards	Title of Standard
Bioburden test	ISO 11737-1:2018+AMD1:2021	Sterilization of health care products - Microbiological methods - Part 1:
		Determination of a population of microorganisms on products [Including Amendment 1 (2021)]
Sterility test	ISO 11737-2:2019	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EO and ECH residue test	ISO 10993-7:2008+AMD1:2019	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Amendment 1: Applicability of allowable limits for neonates and infants]
Bacterial endotoxins test	USP <85>	Bacterial Endotoxins Test

- The test samples were subjected to simulated distribution testing in compliance with ISTA 3A:2018. Package integrity testing was conducted according to the following standards. The test results demonstrated that the packaging was acceptable for protection of product and sterility maintenance.

Test item	Complied standards
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>

- The accelerated aging test was conducted to evaluate the shelf-life of the device in accordance with the calculation method for accelerated aging duration specified in ASTM F1980-21. Packaging integrity testing and product performance testing were performed on the samples after accelerated aging. The test results indicated that the device shelf-life could be determined to be 5 years.

10. Clinical Test Conclusion

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

11. Conclusion

The Profoject™ Disposable Syringe and the Profoject™ Disposable Syringe with 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 predicate device.