July 18, 2025

CMT Health PTE. Ltd.
Monica Ma
Sponsor/Applicant
150 Beach Road, #28-05, Gateway West
Singapore, 189720
Singapore

Re: K251585
Trade/Device Name: Profoject™ Enteral Feeding Syringe
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: Class II
Product Code: PNR
Dated: May 23, 2025
Received: May 23, 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,

STEPHANIE COLE -S

for Anthony C. Lee, Ph.D., M.B.A.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity, and Transplant Devices
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.	K251585

Please provide the device trade name(s).

Profoject™ Enteral Feeding Syringe

Please provide your Indications for Use below.

The device is intended for use as a dispenser, a measuring device and an oral fluid transfer device. It is intended to be used to deliver fluids into the body orally or enterally. It is intended to be used in clinical or home care settings by operators ranging from qualified medical practitioners to laypersons (under the supervision of a qualified medical practitioners) in all age groups.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

1. Submission Information

510(k) Number:	K251585
Date:	May 23, 2025
Type of 510(k) Submission:	Traditional
Submitter:	CMT HEALTH PTE. LTD. 150 BEACH ROAD, #28-05, GATEWAY WEST, SINGAPORE, 189720 Contact Person: Monica Ma E-mail: ra@cmthealth.com Tel: +65 6846 1379

2. Device Identification

Trade Name:	Profoject™ Enteral Feeding Syringe
Common Name:	Enteral Syringes With Enteral Specific Connectors
Regulation Name:	Gastrointestinal tube and accessories
Product Code:	PNR
Device Class:	II
Regulation Number:	21CFR 876.5980
Review Panel:	Gastroenterology/Urology
Indications for use:	The device is intended for use as a dispenser, a measuring device and an oral fluid transfer device. It is intended to be used to deliver fluids into the body orally or enterally. It is intended to be used in clinical or home care settings by operators ranging from qualified medical practitioners to laypersons (under the supervision of a qualified medical practitioners) in all age groups.
Device Description:	Profoject™ Enteral Feeding Syringe provided in a variety of sizes from 0.5mL to 60mL. It consists of plunger, plunger stopper, barrel, and used to deliver fluids into the body orally or connected to an enteral access device with male ENFit connector. The proposed syringe is sterile or non-sterile. Sterile device was sterilized by Ethylene Oxide Gas to achieve a SAL of 10^{-6} and supplied sterility maintenance package. The shelf life of both sterile and non-sterile proposed devices has been validated as 5 years.

3. Predicate Device Identification

K211025 - Oral/Enteral Syringe with ENFit connector

4. Non-Clinical Test Conclusion

Non-clinical verification of the Enteral Feeding Syringe has been conducted to evaluate their safety, performance, and functionality. The results of these tests have demonstrated the overall safety of the proposed 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 proposed device in accordance with relevant test methods cited below:

Performance Testing

1. ISO 20695 First edition 2020-03 Enteral feeding systems - Design and testing
2. ISO 7886-1 Second edition 2017-05 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
3. ISO 80369-1 Second edition 2018-11 Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements
4. ISO 80369-3 First Edition 2016-07-01 Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications [Including AMENDMENT 1 (2019)].
5. ISO 80369-20 First edition 2015-05-15 Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods
6. ISO 11737-1 Third edition 2018-01 [Including AMD1:2021] Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product [Including Amendment 1 (2021)]
7. USP - NF <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms
8. ASTM F1886/F1886M-16 (2024) Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
9. ASTM F1140/F1140M-13 (2020) Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
10. ASTM F88/F88M-23 Standard Test Method for Seal Strength of Flexible Barrier Materials
11. ASTM F1929-23 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
12. USP - NF <71> Sterility Tests
13. ISO 10993-7 Second edition 2008-10-15 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
14. ISO 11135 Second edition 2014-07-15 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]
15. ISTA 3A: 2018 Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less
16. Safety Considerations to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral Applications - Guidance for Industry and Food and Drug Administration Staff

In addition, dose accuracy testing is conducted to demonstrate the enteral syringes are accurate to ±10% when the syringe is filled with a minimum dose of 20% of the overall syringe capacity.

Biocompatibility Testing

The biocompatibility evaluation for the Enteral Feeding Syringe 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 proposed device is classified as a surface device, mucosal membrane contact.

1. ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
2. ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
3. ISO 10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation

6. Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data was not including in this submission

7. Substantially Equivalent Comparison Conclusion

Parameters		Proposed Device	Predicate Device	Remark
1	510(k) Number	K251585	K211025	--
2	510(k) Holder	CMT HEALTH PTE. LTD.	Ningbo Tianyi Medical Appliance Co., Ltd.	--
3	Trade Name	Profoject™ Enteral Feeding Syringe	Oral/Enteral Syringe with ENFit connector	--
4	Product Code	PNR	PNR	Same
5	Regulation Number	21CFR 876.5980	21CFR 876.5980	Same
6	Review Panel	Gastroenterology/Urology	Gastroenterology/Urology	Same
7	Device Class	II	II	Same
8	Indications for use	The device is intended for use as a dispenser, a measuring device and an oral fluid transfer device. It is intended to be used to deliver fluids into the body orally or enterally. It is intended to be used in clinical or home care settings by operators ranging from qualified medical practitioners to laypersons (under the supervision of a qualified medical practitioners) in all age groups	The device is intended for use as a dispenser, a measuring device and an oral fluid transfer device. It is intended to be used to deliver fluids into the body orally or enterally. It is intended to be used in clinical or home care settings by operators ranging from qualified medical practitioners to laypersons (under the supervision of a qualified medical practitioners) in all age groups	Same
9	Configuration	Plunger stopper; Plunger; Barrel with ENFit connector	Piston; Plunger; Barrel with ENFit connector; Tip cap	Similar Note 1
10	Single Use	Single Use	Single Use	Same
11	Product Size (nominal volumes)	Low dose tip ENFit syringe: 0.5ml, 1ml, 3ml, 5ml, 6ml Standard ENFit syringe: 10ml, 12ml, 20ml, 30ml, 35ml, 50ml, 60ml	Low dose tip ENFit syringe: 0.5ml, 1ml, 3ml, 6ml Standard ENFit syringe: 12ml, 20ml, 35ml, 60ml	Similar Note 2
12	Product Performance	Complied with: ISO 80369-3 ISO 80369-20 ISO 7886-1	Complied with: ISO 80369-3 ISO 80369-20 ISO 7886-1	Same
13	Materials	Barrel: Polypropylene (PP)	Barrel: Polypropylene (PP)	Similar

		Plunger: Polypropylene (PP) and purple color additive Plunger stopper: Polyisoprene rubber	Plunger: Polypropylene (PP) and white pigment Piston: Silicone rubber Tip Cap: Polypropylene (PP) and Orange pigment Or polypropylene (PP) and purple pigment	Note 3
14	Biocompatibility	No Cytotoxicity No Irritation No Sensitization	No Cytotoxicity No Irritation No Sensitization	Same
15	Sterile	Sterile or non-sterile	Sterile or non-sterile	Same
16	Sterile Method	EO Sterilized	EO Sterilized	Same
17	Sterilization	EO (ethylene gas) to SAL=10^{-6}	EO (ethylene gas) to SAL=10^{-6}	Same

Differences between proposed device and predicate device, reference device:

Note 1:

The configuration of proposed device is different from predicate device, depending on the design and sales requirements of the product. According to ISO 20695, enteral syringes shall consist of at least the following: a) a graduated container; b) unless the enteral syringe is designed for gravity use, there shall be a means to create pressure (e.g.a plunger or a bulb); c) an outlet port. Tip cap is not a required component, it will not affect the safety and effectiveness of the proposed device.

Note 2:

The product size for proposed device is different from predicate device and this difference is just in infusion capacity and dose not effect indication for use, the physician can select by per patient's condition. And through performance test reports that proposed device will not raise safety and effectiveness issues.

Note 3:

The materials of plunger and plunger stopper are different between the proposed device and predicate device. This difference does not raise any new questions of safety and effectiveness. The biocompatibility test of the proposed device was conducted to demonstrate that the proposed device met the biocompatibility requirements.

The Conclusions:

The conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed devices identified in the submission. Thus the subject device is substantially equivalent to the predicate device.