April 8, 2026

CMT Health Pte. Ltd
Monica Ma
Official Correspondent
150 Beach Road, #28-05, Gateway West
Singapore, 189720
Singapore

Re: K253268
Trade/Device Name: Profoject Enteral/Oral Feeding Syringe; Profoject Reusable Enteral/Oral Feeding Syringe (Model A, Model B); Profoject ENFit Adaptor; Profoject Enteral Feeding Syringes Cap
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube And Accessories
Regulatory Class: Class II
Product Code: PNR, PIO
Dated: September 29, 2025
Received: September 29, 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 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,

ANTHONY LEE -S

Anthony 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.	K253268

Please provide the device trade name(s).

Profoject™ Enteral/Oral Feeding Syringe;
Profoject™ Reusable Enteral/Oral Feeding Syringe (Model A, Model B);
Profoject™ ENFit Adaptor;
Profoject™ Enteral Feeding Syringes Cap

Please provide your Indications for Use below.

Profoject™ Enteral/Oral Feeding Syringe:
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 and non-clinical settings by users ranging from clinicians to laypersons in all age groups.

Profoject™ Reusable Enteral/Oral Feeding Syringe:
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 multiple times in clinical and non-clinical settings by users ranging from clinicians to laypersons in all age groups. The device is indicated for single patient use only.

Profoject™ ENFit Adaptor:
The device is intended for connecting an enteral giving set with an ENFit connector to an enteral catheter with funnel.

Profoject™ Enteral Feeding Syringes Cap:
The Profoject™ Enteral Feeding Syringes Cap is used to prevent fluid loss and contamination of syringe contents until ready for use.

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

[As required by 21 CFR 807.92]

1. Submission Information

510(k) Number:	K253268
Date:	September 29, 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 Description

Proprietary Name:	Profoject™ Enteral/ Oral Feeding Syringe, Profoject™ Reusable Enteral/ Oral Feeding Syringe, Profoject™ ENFit Adaptor, Profoject™ Enteral Feeding Syringes Cap
Common Name:	Enteral Syringes With Enteral Specific Connectors, Enteral Specific Transition Connectors
Regulation Name:	Gastrointestinal tube and accessories
Product Code:	PNR, PIO
Device Class:	II
Regulation Number:	21CFR 876.5980
Review Panel:	Gastroenterology/Urology
Indications for use:	Profoject™ Enteral/ Oral Feeding Syringe: 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 non-clinical settings by users ranging from clinicians to laypersons in all age groups. Profoject™ Reusable Enteral/ Oral Feeding Syringe: 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 multiple times in clinical and non-clinical settings by users ranging from clinicians to laypersons in all age groups. The device is indicated for single patient use only. Profoject™ ENFit Adaptor: The Profoject™ ENFit Adaptor is intended for connecting an enteral giving set with an ENFit connector to an enteral catheter with funnel. Profoject™ Enteral Feeding Syringes Cap: The Profoject™ Enteral Feeding Syringes Cap is used to prevent fluid loss and contamination of syringe contents until ready for use.

Device Description:

Profoject™ Enteral/ Oral Feeding Syringe:
Profoject™ Enteral/Oral Feeding Syringe s a disposable device designed for enteral and oral feeding, available in transparent and amber options and offered in multiple sizes ranging from 0.5 mL to 60 mL. It consists of plunger, plunger stopper, barrel, and it is used to deliver fluids into the body orally or connected to an enteral access device with male ENFit connector. Available with and without adaptor or syringes cap.

Profoject™ Reusable Enteral/ Oral Feeding Syringe:
The Profoject™ Reusable Enteral/Oral Feeding Syringe is a reusable device designed for enteral and oral feeding, available in multiple sizes ranging from 1 mL to 60 mL. It is offered in two models—Model A and Model B—with each model available in both transparent and amber products. The syringe comprises a plunger, O-ring gasket, and barrel, and is intended for the administration of fluids either orally or via connection to an enteral access device using a male ENFit connector.

Profoject™ ENFit Adaptor:
Profoject™ ENFit Adaptor is a disposable adaptor used to connect an enteral giving set with an ENFit connector to an enteral catheter with funnel. To facilitate the interconnection between newer devices having end ENFit connectors and the funnel feeding ports with existing ('legacy') end connectors, the adaptor is designed with two ports. One port is a male connector that complies with the ISO 80369-3 standard and can be directly connected to the corresponding female ENFit connector; the other port is a stepped connector that can adapt to previously used end connectors. The adaptor can supply with the feeding syringes or sold separately (sterile or non-sterile).

Profoject™ Enteral Feeding Syringes Cap:
Profoject™ Enteral Feeding Syringes Cap is a disposable tip cap used to prevent fluid loss and contamination of syringe contents until ready for use. The device has four model types: Model I, Model II, Model III and Model IV. The cap can supply with the feeding syringes or sold separately (sterile or non-sterile).

The proposed devices are available in sterile and non-sterile types. Sterile devices are sterilized by ethylene oxide gas to achieve a SAL of 10-6. The validity periods of both sterile and non-sterile products have been verified to be 5 years.

3. Predicate Device Identification

K183540 - Oral/Enteral Syringes with ENFit connector (12 mL to 60 mL), Low Dose Tip Oral/Enteral Syringes with ENFit connector (1 mL to 6 mL)
K140581 - Cedic Enteral Distal End ENFit Transition Connector, Cedic Enteral ENFit Transition Connector for Medication Port
K152857 - NeoMed NeoConnect Enteral Syringes with ENFit Connector and compatible NeoSecure Tip Caps

4. Non-Clinical Test Conclusion

Non-clinical verification of the proposed devices 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
17. Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff
18. ASTM ST98:2022 Cleaning validation of health care products – requirements for development and validation of a cleaning process for medical devices
19. USP - NF <1111> Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use
20. USP - NF <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests

Biocompatibility Testing

The biocompatibility evaluation for the proposed devices 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 devices are 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
4. USP <151> Rabbit Pyrogen Study
5. ISO 10993-11 Third edition 2017-09 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
6. ISO 10993-4 Third edition 2017-04 Biological evaluation of medical devices--Part 4: Selection of tests for interactions with blood
7. ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials

6. Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data was not included in this submission

7. Substantially Equivalent Comparison Conclusion

Table 1 Device comparison table for Profoject™ Enteral/Oral Feeding Syringe and Profoject™ Reusable Enteral/Oral Feeding Syringe

Parameters		Proposed Device	Predicate Device	Remark
1	510(k) Number	K253268	K183540	--
2	510(k) Holder	CMT HEALTH PTE. LTD.	NeoMed, Inc.	--
3	Trade Name	Profoject™ Enteral/ Oral Feeding Syringe, Profoject™ Reusable Enteral/ Oral Feeding Syringe	Oral/Enteral Syringes with ENFit connector (12 mL to 60 mL), Low Dose Tip Oral/Enteral Syringes with ENFit connector (1 mL to 6 mL)	--
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	Profoject™ Enteral/Oral Feeding Syringe: 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 and non-clinical settings by users ranging from clinicians to laypersons in all age groups. Profoject™ Reusable/Oral Enteral Feeding Syringe: 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 multiple times in clinical and non-clinical settings by users	Single Use Oral/Enteral Syringes with ENFit Connector (provided sterile and non-sterile): 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 and non-clinical settings by users ranging from clinicians to laypersons in all age groups. Reusable Oral/Enteral Syringes with ENFit Connector (provided non-sterile): The device is intended for use as a dispenser, a measuring device and an oral fluid transfer device. It is intended to be used	Similar Note 1

		ranging from clinicians to laypersons in all age groups. The device is indicated for single patient use only.	multiple times in non-clinical settings by users ranging from clinicians to laypersons in all age groups. The device is indicated for single patient use only.	
9	Target Population	All age groups	All age groups	Same
10	Single Use	Single use or single patient use	Single use or single patient use	Same
11	Configuration	Plunger stopper or gasket Plunger Barrel with ENFit connector Syringes cap (optional) ENFit adaptor (optional)	Gasket Plunger Barrel with ENFit connector	Similar Note 2
12	Material	Polypropylene Polyisoprene rubber or Silicone Purple color additive Amber color additive	Polypropylene Silicone Polydimethylsiloxane White Colorant	Similar Note 3
13	Product Size (nominal volumes)	Low dose tip ENFit syringe: 0.5ml, 1ml, 3ml, 5ml, 6ml	Low dose tip ENFit syringe: 1ml to 6ml	Similar Note 4
		Standard ENFit syringe: 5ml, 6ml, 10ml, 12ml, 20ml, 30ml, 35ml, 50ml, 60ml	Standard ENFit syringe: 12ml to 60ml	
14	Product Performance	Complied with: ISO 80369-3 ISO 7886-1	Complied with: ISO 80369-3 ISO 7886-1	Same

15	Biocompatibility	No Cytotoxicity No Irritation No Sensitization No Acute Toxicity No Pyrogenicity No Subacute Toxicity	No Cytotoxicity No Irritation No Sensitization No Acute Toxicity	Similar Note 5
16	Sterile	Sterile or non-sterile	Sterile or non-sterile	Same
17	Sterile Method	EO Sterilized (Only sterile device)	EO Sterilized (Only sterile device)	Same
18	Sterilization	EO (ethylene gas) to SAL=10^{-6} (Only sterile device)	EO (ethylene gas) to SAL=10^{-6} (Only sterile device)	Same

Note 1

For sterilized reusable products, performance tests are conducted in accordance with ISO 80369-3 and ISO 7886-1 standards, and residual levels of ethylene oxide (EO) and ethylene chlorohydrin (ECH) are tested per ISO 10993-7:2008/Amd.1:2019 standard. For non-sterile reusable products, performance tests are carried out in line with ISO 80369-3 and ISO 7886-1 standards, and microbial testing is performed per ISO 11737-1 standard.

Through cleaning validation and maximum re-use cycle verification, the proposed device can meet the needs of multiple uses without introducing additional cross-contamination risks, thus being suitable for use in both clinical and non-clinical settings.

Note 2

The configuration of proposed device is different from predicate device, but the proposed device of the structure has passed the verification of ISO 80369-3, ISO 80369-20 and ISO 7886-1. 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. Syringe cap and ENFit Adaptor are not required components, it will not affect the safety and effectiveness of the proposed device.

Note 3

Through the biocompatibility test, the results confirmed that the materials of the proposed device will not cause any safety issues and effectiveness issues.

Note 4

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 5

According to the guideline documents, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", proposed device added pyrogen test and subacute toxicity test. The test results comply with the requirements of the standard.

Table 2 Device comparison table for Profoject™ ENFit Adaptor

Parameters		Proposed Device	Predicate Device	Remark
1	510(k) Number	K253268	K140581	--
2	510(k) Holder	CMT HEALTH PTE. LTD.	CEDIC S.R.L.	--
3	Trade Name	Profoject™ ENFit Adaptor	Cedic Enteral Distal End ENFit Transition Connector, Cedic Enteral ENFit Transition Connector for Medication Port	--
4	Product Code	PIO	PIO	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 Profoject™ ENFit Adaptor is intended for connecting an enteral giving set with an ENFit connector to an enteral catheter with funnel.	The Cedic Enteral Distal End ENFit Transition Connector is intended for connecting an enteral giving set with an ENFit connector to an enteral catheter with funnel. Cedic Enteral ENFit Transition Connector For Medication Port: Intended for connecting a male oral tip syringe to an enteral giving set or enteral catheter with an ENFit medication port. Available with and without end cap. Cedic Enteral Funnel ENFit Transition Connector: Intended for connecting an enteral giving set equipped with a stepped enteral distal end to an enteral catheter equipped with an ENFit connector. Available with and without end cap.	Same
9	Environment of Use	Hospital - Home	Hospital - Home	Same
10	User population	Healthcare professionals or layusers	Healthcare professionals or layusers	Same
11	Single Use	Single use	Single use	Same
12	Rx vs. OTC	Rx	Rx	Same

13	Material	ABS; LDPE; Purple color additive	ABS HF 380 LDPE (Riblene MM20) Soft PVC (Nakan FMA919N) Remafin Violet PE43076356-ZT **(**2%)	Similar Note 1
14	Product Performance	Complied with: ISO 80369-3 ISO 80369-20	Complied with: ISO 80369-3 ISO 80369-20	Same
15	Expiration Date	5 years	3 years	Similar Note 2
16	Sterile	Sterile or non-sterile	Non-sterile	Similar Note 3

Note 1

Through the biocompatibility test, the results confirmed that the materials of the proposed device will not cause any safety issues and effectiveness issues.

Note 2

The expiration date for proposed device is different from predicate device and performance testing proves that proposed devices still meet ISO 80369-3 and ISO 80369-20 requirements after 5 years of accelerated aging. Therefore, this difference does not raise new safety and effectiveness issues.

Note 3

For non-sterile proposed devices, performance testing has demonstrated that non-sterile proposed devices meet ISO 80369-3 and ISO 80369-20 requirements, and microbiological testing has demonstrated that microbial counts are within acceptable limits.

For sterile proposed devices, perform performance tests in accordance with ISO 80369-3 and ISO 7886-1 standards and test the residual levels of EO and ECH in accordance with ISO 10993-7:2008/Amd.1:2019 standards. The test results all meet the requirements of the corresponding standards; therefore, this difference does not raise new safety and effectiveness issues.

Table 3 Profoject™ Enteral Feeding Syringes Cap

Parameters		Proposed Device	Predicate Device	Remark
1	510(k) Number	K253268	K152857	--
2	510(k) Holder	CMT HEALTH PTE. LTD.	NEOMED, INC.	--
3	Trade Name	Profoject™ Enteral Feeding Syringes Cap	NeoMed NeoConnect Enteral Syringes with ENFit Connector and compatible NeoConnect™ NeoSecure™ Tip Cap	--
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 Profoject™ Enteral Feeding Syringes Cap is used to prevent fluid loss and contamination of syringe contents until ready for use.	A NeoConnect™ Enteral Syringe with ENFit™ connector accessory used to prevent fluid loss and contamination of syringe contents until ready for use.	Same
9	Rx vs OTC	OTC	Rx	Note 1
10	Target Population	All age groups	All age groups	Same
11	Single Use	Single use	Single use	Same
12	Material	LDPE TPE Polypropylene Purple color additive Orange color additive	Polypropylene Color additive	Similar Note 2
13	Connection	Male ENFit	Male ENFit	Same
14	Product Performance	Complied with: ISO 80369-3 ISO 20695	Unknown	Note 3
15	Biocompatibility	No Cytotoxicity No Intracutaneous Reactivity No Skin	Unknown	Note 4

		Sensitization		
16	Sterile	Sterile or non-sterile	Sterile or non-sterile	Same
17	Sterile Method	EO Sterilized (Only sterile device)	EO Sterilized (Only sterile device)	Same
18	SAL	10^{-6} (Only sterile device)	10^{-6} (Only sterile device)	Same

Note 1

Based on the risk management, the device can be used safely and effectively by laypersons as OTC device.

Note 2

Through the biocompatibility and performance test according to ISO 80369-3:2016, the results confirmed that the materials of the proposed device will not cause any safety issues and effectiveness issues.

Note 3

The proposed device is designed in accordance with the ENFit specification and complies with ISO 80369-3, a recognized consensus standard for reducing the risk of misconnection. Validation testing conducted in accordance with ISO 20695:2020 and ISO 80369-3:2016 demonstrates that all results meet the requirements of these standards and therefore, the proposed device does not cause safety issues and effectiveness issues.

Note 4

According to ISO 10993-1:2018 and guidance of FDA's "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" | FDA", the proposed device is adjudicated surface device-mucosal membrane indirect-contact time ≤ 24h, tests to be performed are cytotoxicity, skin sensitization and irritation or intracutaneous reactivity. The test results compliant with standard requirements and therefore, the proposed device does not cause safety issues and effectiveness issues.

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 devices are substantially equivalent to the predicate devices.