July 15, 2026

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

Re: K260739
Trade/Device Name: Profoject™ Pen Needles (Model A; Model B)
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: June 16, 2026
Received: June 16, 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,

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)*
K260739

Device Name
Profoject™ Pen Needles (Model A; Model B)

Indications for Use *(Describe)*
Profoject™ Pen Needles are intended for use with pen injector devices for the subcutaneous injection of drugs.

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

1. Submission Information

510(k) Number:	K260739
Date of submission:	March 6, 2026
Type of 510(k) Submission:	Traditional 510(k)
Submitter:	CMT HEALTH PTE. LTD. 150 BEACH ROAD, #28-05, GATEWAY WEST, SINGAPORE, 189720 Contact Person: Monica Ma E-mail: Ra@cmthealth.com Tel: +6568461379

2. Device Description

Trade Name: Profoject™ Pen Needles (Model A; Model B)
Regulation Name: Hypodermic Single Lumen Needle
Device Class: II
Product Code: FMI
Regulation Number: 21 CFR 880.5570
Review Panel: General Hospital
Indications for Use: Profoject™ Pen Needles are intended for use with pen injector devices for the subcutaneous injection of drugs.

Profoject™ Pen Needles are available in two models, Model A and Model B, which share identical components and differ only in dimensional specifications. Both models are supplied sterile and are intended for single-use only. The two models have identical structural composition and consist of the following five components: (1) Needle Container, (2) Needle Shield, (3) Needle Tube, (4) Needle Hub, and (5) Sealed Paper. The Needle Container, together with the Sealed Paper, forms the unit packaging of the Profoject™ Pen Needles and maintains the sterility of the product until use. The Needle Hub is designed to be screwed onto compatible pen injectors.

The specifications are as follows.

Table 1 Specifications for Profoject™ Pen Needles (Model A)

Specifications		Color of Needle Shield	Specifications		Color of Needle Shield
1	0.18mm(34G)×4mm TW	Brown	13	0.25mm(31G)×8mm TW	Orange
2	0.20mm(33G)×4mm TW	Pink	14	0.30mm(30G)×4mm TW	Deep Purple

3	0.20mm(33G)×5mm TW	Warm gray	15	0.30mm(30G)×5mm TW	Red
4	0.20mm(33G)×6mm TW	Brown	16	0.30mm(30G)×6mm TW	Black
5	0.20mm(33G)×8mm TW	Cream	17	0.30mm(30G)×8mm TW	Yellow
6	0.23mm(32G)×4mm TW	Light green	18	0.30mm(30G)×10mm TW	Deep green
7	0.23mm(32G)×5mm TW	gray	19	0.33mm(29G)×4mm TW	Deep red
8	0.23mm(32G)×6mm TW	Pale Brown	20	0.33mm(29G)×5mm TW	White
9	0.23mm(32G)×8mm TW	Blue-green	21	0.33mm(29G)×8mm TW	Brown
10	0.25mm(31G)×4mm TW	Light blue	22	0.33mm(29G)×10mm TW	Light purple
11	0.25mm(31G)×5mm TW	Purple	23	0.33mm(29G)×12mm TW	Red
12	0.25mm(31G)×6mm TW	Deep blue	/	/	/

Table 2 Specifications for Profoject™ Pen Needles (Model B)

Specifications		Color of Needle Shield	Specifications		Color of Needle Shield
1	0.18mm(34G)×4mm RW	Brown	30	0.30mm(30G)×4mm TW	Deep Purple
2	0.18mm(34G)×4mm TW	Brown	31	0.30mm(30G)×5mm RW	Red
3	0.18mm(34G)×5mm RW	Magenta	32	0.30mm(30G)×5mm TW	Red
4	0.18mm(34G)×5mm TW	Magenta	33	0.30mm(30G)×6mm RW	Black
5	0.20mm(33G)×4mm RW	Pink	34	0.30mm(30G)×6mm TW	Black
6	0.20mm(33G)×4mm TW	Pink	35	0.30mm(30G)×8mm RW	Yellow
7	0.20mm(33G)×5mm RW	Warm gray	36	0.30mm(30G)×8mm TW	Yellow
8	0.20mm(33G)×5mm TW	Warm gray	37	0.30mm(30G)×10mm RW	Deep green
9	0.20mm(33G)×6mm RW	Brown	38	0.30mm(30G)×10mm TW	Deep green
10	0.20mm(33G)×6mm TW	Brown	39	0.33mm(29G)×4mm RW	Deep red
11	0.20mm(33G)×8mm RW	Cream	40	0.33mm(29G)×4mm TW	Deep red
12	0.20mm(33G)×8mm TW	Cream	41	0.33mm(29G)×5mm RW	White
13	0.23mm(32G)×4mm RW	Light green	42	0.33mm(29G)×5mm TW	White
14	0.23mm(32G)×4mm TW	Light green	43	0.33mm(29G)×6mm RW	Blue-gray
15	0.23mm(32G)×5mm RW	gray	44	0.33mm(29G)×6mm TW	Blue-gray
16	0.23mm(32G)×5mm TW	gray	45	0.33mm(29G)×8mm RW	Brown
17	0.23mm(32G)×6mm RW	Pale Brown	46	0.33mm(29G)×8mm TW	Brown
18	0.23mm(32G)×6mm TW	Pale Brown	47	0.33mm(29G)×10mm RW	Light purple
19	0.23mm(32G)×8mm RW	Blue-green	48	0.33mm(29G)×10mm TW	Light purple
20	0.23mm(32G)×8mm TW	Blue-green	49	0.33mm(29G)×12mm RW	Red
21	0.25mm(31G)×4mm RW	Light blue	50	0.33mm(29G)×12mm TW	Red
22	0.25mm(31G)×4mm TW	Light blue	51	0.36mm(28G)×4mm RW	Cool Gray
23	0.25mm(31G)×5mm RW	Purple	52	0.36mm(28G)×4mm TW	Cool Gray
24	0.25mm(31G)×5mm TW	Purple	53	0.36mm(28G)×5mm RW	Green-yellow
25	0.25mm(31G)×6mm RW	Deep blue	54	0.36mm(28G)×5mm TW	Green-yellow
26	0.25mm(31G)×6mm TW	Deep blue	55	0.36mm(28G)×6mm RW	Olive green
27	0.25mm(31G)×8mm RW	Orange	56	0.36mm(28G)×6mm TW	Olive green

28	0.25mm(31G)×8mm TW	Orange	57	0.36mm(28G)×8mm RW	Cobalt blue
29	0.30mm(30G)×4mm RW	Deep Purple	58	0.36mm(28G)×8mm TW	Cobalt blue

3. Identification of Predicate Device

Predicate Device
510(k) Number: K171982
Product Name: Droplet® Pen Needles

4. Substantially Equivalent Comparison

Parameters		Proposed Device	Predicate Device	Remark
1	510(k) Number	K260739	K171982	/
2	510(k) Holder	CMT HEALTH PTE. LTD.	HTL-STREFA S.A.	/
3	Trade Name	Profoject™ Pen Needles	Droplet® Pen Needles	/
4	Product code	FMI	FMI	Same
5	Regulation No.	21 CFR 880.5570	21 CFR 880.5570	Same
6	Classification Name	Hypodermic Single Lumen Needle	Hypodermic Single Lumen Needle	Same
7	Regulation Class	II	II	Same
8	Indications for use	Profoject™ Pen Needles are intended for use with pen injector devices for the subcutaneous injection of drugs.	Droplet® Pen Needles are intended for use with pen injector devices for the subcutaneous injection of drugs.	Same
9	Prescription/OTC	OTC	OTC	Same
10	Supplied sterile	Yes	Yes	Same
11	Single use	Yes	Yes	Same
12	Principle of operation	Manual	Manual	Same
13	Method of attachment to pen injector	Screw threads	Screw threads	Same
14	Models	Model A Length: 4mm, 5mm, 6mm, 8mm, 10mm, 12mm Gauge: 29G, 30G, 31G, 32G, 33G, 34G Model B Length: 4mm, 5mm, 6mm, 8mm, 10mm, 12mm	Length: 4mm, 5mm, 6mm, 8mm, 10mm, 12mm Gauge: 29G, 31G, 32G	Different See discussion 1

		Gauge: 28G, 29G, 30G, 31G, 32G, 33G, 34G		
15	Wall types	Regular wall (RW), Thin wall (TW)	Not disclosed	Different See discussion 2
16	Biocompatibility	Conform with ISO 10993 standards	Conform with ISO 10993 standards	Same
17	Sterility	SAL=10^{-6}	SAL=10^{-6}	Same
18	Sterilization method	EO sterilized	Gamma irradiation	Different See discussion 3
19	Shelf Life	5 years	5 years	Same
20	Unit Packaging	1) Polypropylene 2) Needle container with seal made of dialysis paper	1) Polypropylene 2) container with seal made of medical grade paper	Different See discussion 4
21	Material	1) Needle Tube: 304 Stainless steel 2) Needle Hub and Needle Container: Polypropylene 3) Needle Shield: High Density Polyethylene/Polypropylene 4) Sealed Paper: Dialysis paper 5) Needle point lubricant: Polydimethylsiloxanes	1) Needle Tube: Medical Grade Stainless Steel 2) Needle Hub, Needle Container, Needle Shield: Plastic resins 3) Lubricant: Medical grade silicone	Different See discussion 5
22	Configuration	1) Needle Tube 2) Needle Hub 3) Needle Container 4) Needle Shield 5) Sealed Paper	1) Needle Tube 2) Needle Hub 3) Needle Container 4) Needle Shield	Different See discussion 6
23	Performance Testing	Complied with: ISO 11608-2:2022 ISO 9626	Complied with: ISO 11608-2:2012 ISO 9626 ISO 7864	Different See discussion 7

Discussion in details:

Discussion 1 - Models

The models of proposed devices are different from the predicate device. However, this difference is just in dimension. Different gauges, length and wall of needle tube will be selected by physician per patient's condition. This difference does not affect intended use. In addition, bench performance tests were conducted on the proposed device and the results met the requirements in the standards. Therefore, the differences in models do not raise different questions of safety and effectiveness when compared to the predicate device.

Discussion 2 - Wall types

The needle wall types of proposed device include regular wall and thin wall, while the wall types of the predicate device are not disclosed in public documents. However, this difference is just in wall thickness. This difference does not affect intended use. In addition, bench performance tests were conducted on the proposed device and the results met the requirements in the standards. Therefore, the differences in wall types do not raise different questions of safety and effectiveness when compared to the predicate device.

Discussion 3 - Sterilization method

The sterilization method of proposed device is EO, the sterilization method of predicate device is gamma irradiation. Both achieve a Sterility Assurance Level (SAL) of 10^{-6}. Examination of the EO and ECH residuals have met with prolonged exposure devices allowable limits of ISO 10993-7 AMD 1:2019, this sterilization method difference does not raise different questions of safety and effectiveness when compared to the predicate device.

Discussion 4 - Unit Packaging

The sealing material of the proposed device is dialysis paper, which is a commonly used material in sterile barrier systems for single-use medical devices. The dialysis paper has been validated through manufacturing process validation and demonstrated the performance in terms of microbial barrier and breathability. It meets the requirements of ISO 11607 and ensures compatibility with the sterilization process. In addition, packaging integrity and sterility tests have been conducted. Therefore, the use of this material does not raise different questions of safety and effectiveness when compared to the predicate device.

Discussion 5 - Material

There are differences between the materials of the proposed device and those of the predicate device. However, the proposed devices demonstrated that they complied with ISO 10993 series standards. In addition, bench performance tests were conducted on the proposed device and the results met the requirements in the standards. Therefore, the difference on material does not raise different questions of safety and effectiveness when compared to the predicate device.

Discussion 6 - Configuration

The only configuration difference between the proposed device and the predicate device is the presence of a sealed paper in the proposed device. The sealed paper is only used as a packaging component to maintain sterility prior to use and is removed before the device is applied. This difference does not change the intended use of the device and does not affect its performance or biocompatibility. Therefore, the difference in configuration does not raise different questions of safety and effectiveness when compared to the predicate device.

Discussion 7 - Performance Testing

The predicate device was evaluated according to ISO 11608-2:2012, which required compliance with ISO 7864:1993 for the “freedom-from-defects” criterion. The proposed device was evaluated in

accordance with the updated ISO 11608-2:2022, where this requirement is incorporated directly under Clause 5.2.5 without reference to ISO 7864.

Although different versions of ISO 11608-2 were applied, both include equivalent "freedom-from-defects" criteria. The proposed device follows the updated and consolidated version of the standard, and this difference does not raise different questions of safety and effectiveness when compared to the predicate device.

5. Substantial Equivalent Based on Assessment of Clinical Performance Data

Not applicable.

6. Non-Clinical Test

Non-clinical verification of the Profoject™ Pen Needles have 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 9626 Second edition 2016-08-01 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods.
2) ISO 11608-2:2022 Needle-based injection systems for medical use - Requirements and test methods - Part 2: Double-ended Pen Needles.
3) ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection.
4) ASTM F88/F88M-23 Standard Test Method for Seal Strength of Flexible Barrier Materials.
5) ASTM F1929-23 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.
6) ASTM F1140/F1140M - 13 (2020) e1 Standard test methods for internal pressurization failure resistance of unrestrained packages.
7) ISO 10993-7 Second edition 2008-10-15 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals.
8) ISTA 3A: 2018 Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less.
9) 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)].
10) USP - NF <788> Particulate Matter in Injections.
11) USP - NF <85> Bacterial Endotoxin Testing.
12) USP - NF <71> Sterility Tests.

- Biocompatibility Testing

The biocompatibility evaluation for the Profoject™ Pen Needles were 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 an externally communicating with prolonged, blood path indirect 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

Conclusion:

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Profoject™ Pen Needles are substantially equivalent to the predicate device Droplet® Pen Needles with respect to the indications for use, target population, treatment method, and technological characteristics.