June 10, 2026

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

Re: K260855
Trade/Device Name: Profoject™ Safety Pen Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: March 16, 2026
Received: May 22, 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

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.	K260855	?
Please provide the device trade name(s).		?

Profoject™ Safety Pen Needles

Please provide your Indications for Use below.		?

Profoject™ Safety Pen Needles are intended for use with pen injector devices for the subcutaneous injection of drugs. The device is intended for use in patients weighing ≥ 3.5 kg, from neonates to adults.

Please select the types of uses (select one or both, as applicable).	☐ Prescription Use (21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)	?
Please select the age group(s) for which the device(s) is to be used.	☒ Neonates/Newborns (Birth to < 29 days old) ☒ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)	?

510(k) Summary

[As required by 21 CFR 807.92]

1. Submission Information

510(k) Number:	K260855
Date:	May 22, 2026
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™ Safety Pen Needles
Common Name:	Hypodermic Single Lumen Needle
Regulation Name:	Needle, hypodermic, Single Lumen
Product Code:	FMI
Device Class:	II
Regulation Number:	21 CFR 880.5570
Review Panel:	General Hospital
Indications for use:	Profoject™ Safety Pen Needles are intended for use with pen injector devices for the subcutaneous injection of drugs. The device is intended for use in patients weighing ≥ 3.5 kg, from neonates to adults.
Device Description:	Compared with traditional pen needles, the Profoject™ Safety Pen Needles incorporate a safety feature to help prevent accidental needle-stick injuries to patients and healthcare professionals. The needle tube is equipped with a needle shield that automatically covers and locks the needle tube after use. During injection, the needle shield retracts as the needle tube is inserted into the skin. Once the injection is completed and the needle tube is withdrawn, the needle shield automatically extends to cover the needle tube. After lockout, the safety pen needle cannot be reused. The Profoject™ Safety Pen Needles are single-use, sterile, disposable medical devices intended for use with compatible pen injectors. The device comprises nine primary components: (1) Housing, (2) Needle shield, (3) Needle hub, (4) Needle tube, (5) Outer container, (6) Spring, (7) Retaining ring, (8) Sliding clasp and (9) Sealed paper. The outer container and sealed paper form the unit packaging of the Profoject™ Safety Pen Needles, maintaining sterility until use. The needle hub is designed to screw onto compatible pen injectors.

3. Predicate Device Identification

Predicate 510(k) Number:	K210748
Marketing clearance date:	May 25, 2022
Product name:	Well-life™ Safety Pen Needles
Manufacturer:	W. L. MED Co., Ltd.

4. Non-Clinical Test Conclusion

Non-clinical verification of the Profoject™ Safety 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 11608-2:2022 Needle-based injection systems for medical use - Requirements and test methods - Part 2: Double-ended Pen Needles.
2. ISO 9626 Second edition 2016-08-01 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
3. ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
4. ASTM F1140/F1140M-13 (2020) Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
5. ASTM F88/F88M-23 Standard Test Method for Seal Strength of Flexible Barrier Materials
6. ASTM F1929-23 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
7. USP - NF <71> Sterility Tests
8. ISO 10993-7 Second edition 2008-10-15 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009), AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)]
9. ISTA 3A: 2018 Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less
10. 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)]
11. USP - NF <788> Particulate Matter in Injections
12. USP - NF <85> Bacterial Endotoxin Testing
13. ISO 23908: 2011 Sharps Injury Protection – Requirements and Test Methods – Sharps Protection Features for Single Use Hypodermic Needles, Introducers for Catheters and Needles Uses for Blood Sampling

Usability Testing

FDA guidance document *Medical Devices with Sharps Injury Prevention Features.*

Biocompatibility Testing

The biocompatibility evaluation for the Profoject™ Safety 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 deviceis 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. ISO 10993-11 Third edition 2017-09 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
5. ISO 10993-4 Third edition 2017-04 Biological evaluation of medical devices--Part 4: Selection of tests for interactions with blood

5. Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data was not including in this submission

6. Substantially Equivalent Comparison Conclusion

Parameters			Proposed Device		Predicate Device		Remark
1	510(k) Number		K260855		K210748		--
2	510(k) Holder		CMT HEALTH PTE. LTD.		W. L. Med Co., Ltd.		--
3	Trade Name		Profoject™ Safety Pen Needles		Well-life™ Safety Pen Needles		--
4	Product code		FMI		FMI		Same
5	Regulation Number		21 CFR 880.5570		21 CFR 880.5570		Same
6	Common Name		Hypodermic Single Lumen Needle		Hypodermic Single Lumen Needle		Same
7	Device Class		II		II		Same
8	Indications for use		Profoject™ Safety Pen Needles are intended for use with pen injector devices for the subcutaneous injection of drugs. The device is intended for use in patients weighing ≥ 3.5 kg, from neonates to adults.		The Well-life safety pen needle is intended for use with pen injector devices for the subcutaneous injection of insulin.		Different Discussion 1
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	Needle Gauge	29G, 30G, 31G, 32G, 33G, 34G		29G, 30G, 31G, 32G, 33G, 34G		Different Discussion 2
		Needle Length	4mm, 5mm, 6mm, 8mm		4mm, 5mm, 6mm, 8mm, 10 mm, 12.7mm		
15	Wall type		Thin-walled Extra-thin-walled		Regular walled Thin-walled		Different Discussion 3
16	Biocompatibility		Conform ISO 10993-1		Conform ISO 10993-1		Same
17	Sterility		SAL=10^{-6}		SAL=10^{-6}		Same
18	Sterilization method		EO sterilized		EO sterilized		Same
19	Shelf Life		5 years		5 years		Same
20	Unit Packaging		Polypropylene container with seal made of dialysis paper		Polypropylene container with seal made of medical grade paper		Different Discussion 4
21	Patient-contact Material		Needle tube	SUS 304	Needle tube	STS 304	Different Discussion 5
			Lubricant	Polydimethylsiloxane	Silicon	Polydimethylsiloxane	
22	Configuration		Housing, Needle shield, Needle hub, Needle tube, Outer container, Spring, Retaining ring, Sliding clasp, and Sealed paper		Needle, Hub, Needle Cap, Sterile Cap, Guide, Safety Cap, and Spring		Different Discussion 6

23	Performance Testing	Comply with ISO 9626, ISO 11608-2 and ISO 23908	Comply with ISO 9626, ISO 11608-2 and ISO 23908	Same
24	Principle of operation for the sharps protection feature	The Profoject™ Safety Pen Needles incorporate a safety feature to help prevent accidental needle-stick injuries to patients and healthcare professionals. The needle tube is equipped with a needle shield that automatically covers and locks the needle tube after use. During injection, the needle shield retracts as the needle tube is inserted into the skin. Once the injection is completed and the needle tube is withdrawn, the needle shield automatically extends to cover the needle tube. After it is locked out, the safety pen needle cannot be reused.	The Well-life™ Safety Pen Needle (i.e., S type) is designed to reduce occurrence of accidental needle sticks from patient end of the needle by providing a shield that covers and locks the needle after use. As the user proceeds with inserting the needle into the skin, the Needle Cap will retract. After the injection is completed and needle is removed from the skin, the safety cap will automatically extend to cover the needle. Once the pen needle is locked out, it can no longer be used.	Different Discussion 7

Differences between proposed device and predicate device:

Discussion 1: Indications for use

The broader indication for use does not introduce new or different questions of safety or effectiveness when compared to the predicate device as the device's mechanism remains unchanged.

Discussion 2: Models

The needle length of the proposed device differs from those of the predicate devices. This difference in needle size does not affect device performance. All needle sizes of the proposed device have been tested, and the results demonstrate that the device meets the performance criteria. Therefore, this difference does not affect the substantial equivalence between the proposed and predicate devices.

Discussion 3: Wall type

The wall thickness of the proposed device differs from that of the predicate device. Both thin-walled and extra-thin-walled needles of the proposed device have been tested, and the results demonstrate that the device meets the performance criteria. Therefore, this difference does not affect the substantial equivalence between the proposed and predicate devices.

Discussion 4: Unit Packaging

While the sealing paper materials of the proposed device and the predicate device differ, performance testing has demonstrated that the proposed device maintains a SAL=10^{-6}. Consequently, the difference in unit packaging materials does not raise new or different questions of safety and effectiveness when compared to the predicate device.

Discussion 5: Patient-contact Material

The needle tube material of the proposed device is designated as "SUS 304" (Japanese Industrial Standard), while that of the predicate device is designated as "STS 304" (Korean Standard). Although the nomenclature differs, both designations refer to the same underlying material: 304 austenitic stainless steel. The chemical composition and mechanical properties of SUS 304 and STS 304 are identical within the allowable tolerances of their respective

standards. In addition, biocompatibility testing and ISO 9626 performance testing have been conducted on the proposed device's needle tube material to demonstrate that it meets biocompatibility and ISO 9626 requirements. This difference does not raise any new or different questions of safety and effectiveness when compared to the predicate device.

Discussion 6: Configuration

The configuration of proposed device is different from predicate device, depending on the design and sales requirements of the product. Performance testing has confirmed that differences in design do not result in any new or different questions of safety or effectiveness when compared to the predicate device.

Discussion 7: Principle of operation for the sharps protection feature

The proposed device and the predicate device operate on the same fundamental principle of action, despite minor differences in component nomenclature (e.g., "needle shield" vs. "needle cap"). In both devices, a passive shield retracts during skin insertion, automatically extends upon needle withdrawal, and locks permanently after use, thereby preventing reuse and reducing the risk of accidental needlestick injuries. The claimed terminological variations do not affect the physical sequence of operation, the clinical functional outcome, or the safety mechanism.

The Conclusions:

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