July 29, 2026

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

Re: K261829
Trade/Device Name: Profoject™ Dual-Safety Pen Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: June 2, 2026
Received: June 2, 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

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.	K261829

Please provide the device trade name(s).

Profoject™ Dual-Safety Pen Needles

Please provide your Indications for Use below.

Profoject™ Dual-Safety Pen Needles are intended for use with pen injector devices for the injection of drugs. The device is intended for use in patients weighing ≥ 3.5 kg, from neonates to adults. Additionally, the attached safety shields automatically lock in place after use and are intended to reduce the occurrence of accidental needle-stick injuries from both the patient end and the pen-connection end of the needle.

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)

K261829 510(k) Summary

1. Date of Preparation

July 29, 2026

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 of Device: Profoject™ Dual-Safety Pen Needles
Common Name: Sterile Disposable Safety Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Review Panel: General Hospital

5. Identification of Predicate Device

510(k) Number: K151311
Trade Name of Device: Safe Block Pen Needle
Common Name: Sterile Disposable Safety Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Review Panel: General Hospital

6. Indications for Use Statement:

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

safety shields automatically lock in place after use and are intended to reduce the occurrence of accidental needle-stick injuries from both the patient end and the pen-connection end of the needle.

7. Device Description

Profoject™ Dual-Safety Pen Needles are intended for use with pen injector devices for the injection of drugs. The product has two safety shields, which lock in place after use (patient end) and upon removal of the needle from the pen injector device (pen-connection end). The locked shields help reduce the occurrence of needle sticks from both ends of the needle.

The Profoject™ Dual-Safety Pen Needles consist of housing, rear needle shield, locking ring, front needle shield, needle hub, needle tube, outer container, rear spring, front spring, and seal paper. They are available in various needle gauges (29G, 30G, 31G, 32G, 33G, 34G), needle lengths (4mm, 5mm, 6mm), and wall thickness (Thin Wall and Extra Thin Wall).

The device is intended for single use only. It is supplied sterile, sterilized by ethylene oxide (EO) with a sterilization assurance level (SAL) of 10^{-6}. The device is provided in a sterility maintenance package, which maintains its sterility throughout its five-year shelf life.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Device feature	**Proposed Device**	**Predicate Device K151311**	**Comment**
Indications for use	Profoject™c Dual-Safety Pen Needles are intended for use with pen injector devices for the injection of drugs. The device is intended for use in patients weighing ≥ 3.5 kg, from neonates to adults. Additionally, the attached safety shields automatically lock in place after use and are intended to reduce the occurrence of accidental needle-stick injuries from both the patient end and the pen-connection end of the needle.	Safe Block Pen Needle is intended for use with pen injector devices for the injection of fluids, including insulin. Additionally, the attached safety shield automatically locks in place and reduces the occurrence of accidental sticks from the patient end of the needle. The shield also serves to conceal the needle before and after injection.	Different See discussion 1
Component	1. Needle tube 2. Needle hub 3. Housing 4. Rear needle shield 5. Locking ring 6. Front needle shield 7. Outer container 8. Rear spring	1. Needle tube 2. Needle hub 3. Needle shield 4. Seal paper 5. Lubricant 6. External cover 7. Ring 8. Primary container	Different See discussion 2

	9. Front spring 10. Seal paper 11. Lubricant	9. Glue 10. Spring	
Safety feature	The product has two safety features to reduce needle sticks. Once the safety features are activated, the product cannot be reused. The principles of the two safety features are as follows. For front safety feature: The front needle shield will hide the needle from the user prior to use. As the user proceeds with inserting the needle into the skin the shield will retract. After the injection is completed and the needle is removed from the skin, the front needle shield will automatically extend to cover the patient-end needle and lock in place. For rear safety feature: Before use, the cartridge-end needle is exposed to penetrate the cartridge septum. When the pen needle is connected to the pen injector device, the pen injector device pushes the rear needle shield and compresses the rear spring, arming the safety feature. After the pen needle is removed from the pen injector device, the rear needle shield will automatically extend to cover the cartridge-end needle and lock in place.	The Safe Block Pen Needle 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. Prior to injection the user will attach the Safe Block Pen Needle to the pen. The shield of Safe Block Pen Needle will hide the needle from the user prior to use. As the user proceeds with inserting the needle into the skin the shield will retract. After the injection is completed and needle is removed from the skin, the shield will automatically extend to cover the needle and lock in place.	Different See discussion 3
Product code	FMI	FMI	Same
Regulation number	21 CFR 880.5570	21 CFR 880.5570	Same
Class	II	II	Same
Prescription/OTC	OTC	OTC	Same
Needle gauge	29G, 30G, 31G, 32G, 33G, 34G	31G	Different See discussion 4
Needle length	4mm, 5mm, 6mm	5 mm, 8 mm	
Needle Wall types	Thin wall and extra thin wall	Not disclosed	

Materials	1. Needle tube: Stainless steel (SUS 304) 2. Needle hub: Polypropylene (PP) 3. Housing: Polycarbonate (PC) 4. Rear needle shield: Polycarbonate (PC) 5. Locking ring: Polycarbonate (PC) 6. Front needle shield: Methyl methacrylate acrylonitrile butadiene styrene (MABS) 7. Outer container: Polypropylene (PP) 8. Rear spring: Stainless steel 9. Front spring: Stainless steel 10. Seal paper: Dialysis paper 11. Lubricant: Polydimethylsiloxane 12. Color additive	1. Needle tube: Stainless Steel 2. Needle hub: Polypropylene (PP) 3. Needle shield: HDPE 4. Seal paper: Medical Paper 5. Lubricant: Silicone oil mixture 6. External cover: Polypropylene (PP) 7. Ring: HDPE 8. Primary container: HDPE 9. Glue: UV acrylate 10. Spring: Stainless Steel 11. Colorants: Pigments for polymer	Different See discussion 5
Single use	Yes	Yes	Same
Performance specifications	Complied with: ISO 11608-2 ISO 9626 ISO 23908	Complied with: ISO 11608-2 ISO 9626 ISO 23908	Same
Sterilization	EO	EO	Same
Pyrogen	Non-pyrogenic	Non-pyrogenic	Same
Biocompatibility	The product has successfully undergone the biocompatibility evaluation required by ISO 10993- 1 for: - Cytotoxicity - Hemocompatibility - Skin sensitization - Intracutaneous reactivity - Acute systemic toxicity - Material pyrogenicity - Subacute systemic toxicity	The product has successfully undergone the biocompatibility evaluation required by ISO 10993- 1 for: - Cytotoxicity, - Hemocompatibility , - Sensitization and skin reactivity - Acute systemic toxicity	Different See discussion 6
Labeling	Meets the requirements of 21 CFR Part 801	Meets the requirements of 21 CFR Part 801	Same

Discussion:

Discussion 1

While the proposed device utilizes the term “drugs” to describe the delivery medium and the predicate device utilizes “fluids, including insulin”, this difference in terminology does not affect the intended use of the device, representing merely a difference in descriptive wording. Both devices are intended for injection via pen injectors to deliver medicinal products in fluid form. Furthermore, although the two devices differ in the description of their safety features, this technological difference does not affect their intended use. The predicate device’s safety shield is designed to reduce needlesticks from the patient end only. In contrast, the proposed device’s Dual-Safety feature extends this protection to also cover the pen-connection end, representing an enhancement of the safety mechanism rather than a change in intended use. Therefore, the two devices have the same intended use.

Discussion 2

The proposed device incorporates two safety features (both patient end and pen-connection end), whereas the predicate device has only a patient-end safety feature. This design difference results in different component configurations between the proposed device and the predicate device. However, the fluid-contacting parts (needle tube, lubricant) are essentially the same. The additional components of the proposed device are for the safety feature design and do not affect the fluid delivery pathway or injection performance. Bench testing confirmed that the proposed device meets the same performance standards (ISO 11608-2, ISO 23908, and ISO 9626) as the predicate device. Thus, the component difference does not raise new questions of safety or effectiveness when compared to the predicate device.

Discussion 3

The predicate device provides a single patient-end safety shield that locks after use. The proposed device incorporates an additional cartridge-end safety shield. The proposed device incorporates a cartridge-end safety shield as an extra design. Both shields operate on the same passive locking principle (spring-assisted automatic extension/retraction). The proposed device complies with the same performance standards as the predicate device (ISO 11608-2, ISO 23908), and bench testing has verified that all applicable requirements are satisfied. Additionally, the proposed device (Profoject™ Dual-Safety Pen Needles) underwent simulated clinical use testing per FDA Guidance *Medical Devices with Sharps Injury Prevention Features (2005)*. The proposed device’s simulated clinical use study demonstrated a 0% failure rate for both the patient-end and pen-connection-end safety shields across all four test conditions (dry hand, wet hand, dry gloved-hand, and wet gloved-hand), with all predefined primary and secondary endpoints met. Therefore, the difference in safety features does not raise new questions of safety or effectiveness when compared to the predicate device.

Discussion 4

The needle gauge and needle length of the proposed device differ from those of the predicate device. Additionally, the needle wall types of the proposed device include thin wall and extra thin wall, whereas the wall types of the predicate device are not disclosed in publicly available documents. However, these differences are just in dimension. These variations are common for pen needles to accommodate different patient needs and injection sites. This difference does not affect the intended use. In addition, bench performance testing in accordance with ISO 9626 and ISO 11608-2 was conducted on the proposed device, and the results met the requirements of the standards. Therefore, the differences in needle gauge, needle length and needle wall type do not raise different questions of safety and effectiveness when compared to the predicate device.

Discussion 5

The proposed device and predicate device differ in some materials. However, the fluid pathway components in both devices utilize stainless steel for the needle tube and silicone oil for lubrication. The specific grades of the predicate's materials are not publicly disclosed. The proposed device has been demonstrated to comply with ISO 10993 series standards. Additionally, bench performance testing of the proposed device satisfies the requirements of ISO 11608-2, ISO 23908, and ISO 9626, which are the identical performance standards applied to the predicate device. Therefore, the difference on material does not raise different questions of safety and effectiveness when compared to the predicate device.

Discussion 6

Compared to the predicate device, material pyrogenicity and subacute systemic toxicity were additionally evaluated for the proposed device. Based on the proposed device's contact duration and nature, all required biocompatibility evaluation endpoints were assessed, and the device was demonstrated to meet the biocompatibility requirements. Therefore, the differences in biological evaluation endpoints do not raise different questions of safety and effectiveness when compared to the predicate device.

9. Performance data

The following tests were performed on the proposed device to demonstrate compliance with applicable standards. The test results support the safety and effectiveness of the device when compared to the predicate device, which, together with the comparison in Table 1, provide the basis for a determination of substantial equivalence to the predicate device.

Biocompatibility testing

In accordance with ISO 10993-1 the proposed device is classified as an externally communicating device, in contact with "Blood path, indirect" with a contact duration of prolonged exposure (> 24 h to 30 d). A biocompatibility evaluation for the proposed device was conducted per ISO 10993-1:2018 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process," and the FDA Guidance document (2023), "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The evaluation results indicated that proposed device's 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:

- ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods
- ISO 11608-2:2022 Needle-based injection systems for medical use - Requirements and test methCods - Part 2: Double-ended pen needles
- ISO 23908:2011 Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

Sterilization, packaging, and shelf-life testing

The sterilization process was validated in accordance with ISO 11135:2014, establishing the routine control and monitoring parameters. Simulated distribution testing and package integrity testing were conducted to demonstrate that the packaging effectively protects the product and maintains sterility. To support the claimed 5-year shelf-life, accelerated aging study was performed, followed by package integrity testing, sterility testing, and bench performance testing, confirming that the device remains functional and sterile throughout its shelf-life.

Sterilization validation	ISO 11135: 2014 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
EO and ECH residue test	ISO 10993-7:2008+AMD1:2019 Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals — AMENDMENT 1: Applicability of allowable limits for neonates and infants
Bacterial endotoxins test	USP <85> Bacterial Endotoxins Test
Package integrity testing	Seal strength ASTM F88/F88M-23 Standard Test Method for Seal Strength of Flexible Barrier Materials Dye penetration ASTM F1929-23 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration Visual inspection ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection Internal pressurization ASTM F1140/F1140M-13 (Reapproved 2020)e1 Standard Test Methods for Internal Pressurization Failure Resistance of Packages
Shelf-life evaluation	Sterility test USP <71> Sterility tests Physical, mechanical, chemical, and package tests were performed on aging samples to verify the claimed shelf-life of the device

Simulated clinical study

Beyond performance testing, a dedicated simulated clinical use study was conducted to evaluate the usability of the proposed device. In alignment with FDA's Medical Devices with Sharps Injury Prevention Features guidance, we carried out a simulated clinical use trial to examine the clinical usability of the dual-safety pen needle's sharps injury prevention mechanisms. Laypersons and healthcare professionals assessed the dual-safety pen needle's performance against predefined pass/fail criteria and provided qualitative feedback on their experience with the device's functional design. A total of 520 devices were tested, and no functional failures were identified throughout the trial.

10. Clinical Test Conclusion

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

11. Conclusion

The Profoject™ Dual-Safety Pen Needles are substantially equivalent to their predicate device. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.