February 23, 2026

CMT Health Pte. Ltd
℅ Dave Yungvirt
CEO
Third Party Review Group, LLC
7 Giralda Farms, Suite 120A
Madison, NJ 07940

Re: K253068
Trade/Device Name: Profoject™ Insulin Syringes; Profoject™ Safelock Disposable Insulin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, MEG
Dated: January 12, 2026
Received: January 12, 2026

Dear Dave Yungvirt:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality 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, Injection Devices
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)*
K253068

Device Name
Profoject™ Insulin Syringes, Profoject™ Safelock Disposable Insulin Syringe

Indications for Use *(Describe)*

Profoject™ Insulin Syringes (Model A):
The Profoject™ Insulin Syringes are intended for subcutaneous injection of U-40 and U-100 insulin in the treatment of diabetes.

Profoject™ Insulin Syringes (Model B):
The Profoject™ Insulin Syringes are intended for subcutaneous injection of U-40 and U-100 insulin in the treatment of diabetes.

Profoject™ Safelock Disposable Insulin Syringe
The device is intended for the delivery of U-40 or U-100 insulin. The needle stick prevention feature of the device, once activated, guards against accidental needle-sticks.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

[As required by 21 CFR 807.92]

1. Submission Information

510(k) Number:	K253068
Date:	13 February 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™ Insulin Syringes, Profoject™ Safelock Disposable Insulin Syringe
Common Name:	Syringe, Piston; Syringe, Antistick
Regulation Name:	Piston syringe
Product Code:	FMF, MEG
Device Class:	II
Regulation Number:	21 CFR 880.5860
Review Panel:	General Hospital

Indications for use - Rx Only:

Profoject™ Safelock Disposable Insulin Syringe	The device is intended for the delivery of U-40 or U-100 insulin. The needle stick prevention feature of the device, once activated, guards against accidental needle-sticks.

Indications for use – Rx and OTC:

Profoject™ Insulin Syringes (Model A)	The Profoject™ Insulin Syringes are intended for subcutaneous injection of U-40 and U-100 insulin in the treatment of diabetes.
Profoject™ Insulin Syringes (Model B)	The Profoject™ Insulin Syringes are intended for subcutaneous injection of U-40 and U-100 insulin in the treatment of diabetes.

Device Description:

Profoject™ Insulin Syringes	Profoject™ Insulin Syringes are categorized into Model A and Model B, the difference is that Model A utilizes an integrated hub and barrel design, and Model B has a separate hub and barrel. The proposed device are 0.3mL, 0.5mL, and 1mL syringes designed for subcutaneous injection of a desired dose of insulin, consisting of needle cap, needle tube, plunger stopper, plunger, barrel and hub (only Model B). Profoject™ Insulin Syringes are sterile, single-use, non-toxic and work on the principle of a piston syringe.
Profoject™ Safelock Disposable Insulin Syringe	The Profoject™ Safelock Disposable Insulin Syringe are 0.3mL, 0.5mL, and 1mL syringes designed for subcutaneous injection of a desired dose of insulin, consisting of needle cap, needle tube, plunger stopper, plunger, barrel, collar and protective shield. The Profoject™ Safelock Disposable Insulin Syringe is a sterile, single-use, non-toxic and work on the

principle of a piston syringe.

3. Predicate Device Identification

Insulin Syringes
K223453 - Insulin Syringe
Safelock Disposable Insulin Syringe
K061492 - Kendall Monoject Magellan Insulin Safety Syringe

4. Non-Clinical Test Conclusion

Non-clinical verification of the Profoject™ Insulin Syringes, Profoject™ Safelock Disposable Insulin Syringe 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 performance of the proposed device in accordance with relevant test methods cited below:

Performance Testing

1. ISO 7864 Fourth edition 2016-08-01 Sterile hypodermic needles for single use - Requirements and test methods
2. ISO 9626 Second edition 2016-08-01 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
3. ISO 8537 Third edition 2016-03-15 Sterile single-use syringes, with or without needle, for insulin
4. 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
5. ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
6. ASTM F1140/F1140M-13 (2020) Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
7. ASTM F88/F88M-23 Standard Test Method for Seal Strength of Flexible Barrier Materials
8. ASTM F1929-23 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
9. USP - NF <71> Sterility Tests
10. ISO 10993-7 Second edition 2008-10-15 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
11. ISTA 3A: 2018 Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less
12. 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)]
13. USP - NF <788> Particulate Matter in Injections
14. USP - NF <85> Bacterial Endotoxin Testing
15. ISO 11607-1 Second edition 2019-02 [Including AMD1:2023] Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including Amendment 1 (2023)]

Usability Testing

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

Biocompatibility Testing

The biocompatibility evaluation for the Profoject™ Insulin Syringes, Profoject™ Safelock Disposable Insulin Syringe 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. 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

5. Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data was not including in this submission

6. Substantially Equivalent Comparison Conclusion

Table 1 - Profoject™ Insulin Syringe

Parameters		**Proposed Device**	**Predicate Device**	**Remark**
1	510(k) Number	K253068	K223453	--
2	510(k) Holder	CMT HEALTH PTE. LTD.	Promisemed Hangzhou Meditech Co., Ltd.	--
3	Trade Name	Profoject™ Insulin Syringes	Insulin Syringe	--
4	Common Name	Syringe, Piston, needle, hypodermic, single lumen	Syringe, Piston, needle, hypodermic, single lumen	Same
5	Regulation Name	Piston Syringe, Hypodermic single lumen needle	Piston Syringe, Hypodermic single lumen needle	Same
6	Product Code	FMF	FMF	Same
7	Regulation Number	21 CFR 880.5860	21 CFR 880.5860	Same
8	Review Panel	General Hospital	General Hospital	Same
9	Device Class	II	II	Same
10	Indications for use	The Profoject™ Insulin Syringes are intended for subcutaneous injection of U-40 and U-100 insulin in the treatment of diabetes.	Insulin Syringe is intended for subcutaneous injection of U-40 and U-100 insulin in the treatment of diabetes.	Same
11	Type of use	Prescription use and over the-counter use	Prescription use and over the-counter use	Same
12	Operating Principle	The insulin is injected to subcutaneous tissue by pushing force generated through pushing plunger of the insulin syringe.	The insulin is injected to subcutaneous tissue by pushing force generated through pushing plunger rod of the insulin syringe.	Same
13	Specific drug use	Insulin	Insulin	Same
14	Volume	0.3ml, 0.5ml, 1ml	0.3ml, 0.5ml, 1ml	Same
15	Gauge	27G, 28G, 29G, 30G, 31G	32G, 31G, 30G, 29G, 28G	Different Note 1
16	Length	6 mm, 8 mm, 10 mm, 13 mm, 15mm	6 mm, 8 mm, 12 mm	
17	Needle cover color	Red (U-40) and orange (U-100)	Red (U-40) and orange (U-100)	Same
18	Lubricant composition	Needle point lubricant: Polydimethylsiloxane Barrel lubricant: Polydimethylsiloxane	Aminofuntional siloxane	Different Note 2
19	Barrel transparency	Transparent	Transparent	Same
20	Biocompatibility	No cytotoxicity No irritation reactivity No significant evidence of skin sensitization	No cytotoxicity No irritation reactivity No significant evidence of skin sensitization	Same

		No significant evidence of systemic toxicity No evidence of Hemolysis No evidence of pyrogens	No significant evidence of systemic toxicity No evidence of Hemolysis No evidence of pyrogens	
21	Materials	Needle Tube: Stainless Steel 304 Barrel: Polypropylene Plunger: Polypropylene Hub: Polypropylene Needle Cap: High Density Polyethylene	Needle: Stainless Steel (SUS304) Barrel: Polypropylene Plunger: Polypropylene Piston: Polyisoprene rubber Needle cap: Polyethylene Protective end cap (only type 8): Polyethylene	Different Note 3
22	Sterilization method and SAL	Sterilized by ethylene oxide gas SAL = 10^{-6}	Sterilized by ethylene oxide gas SAL = 10^{-6}	Same
23	Sterilization method	EO Sterilization	EO Sterilization	Same
24	EO and ECH residues testing	Conform ISO 10993-7	Conform ISO 10993-7	Same
Differences between proposed device and predicate device, reference device:				

Note 1:

The proposed device's needle gauge, and length are different from the predicate device. This difference does not affect intended use. The differences on needle length and gauge does not raise new questions of safety and effectiveness when compared to the predicate device. In addition, differences in needle length and gauge between the predicate and proposed device were addressed through ISO 8537 performance testing.

Note 2:

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

Note 3:

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

Table 2 - Profoject™ Safelock Disposable Insulin Syringe

Parameters		**Proposed device**	**Predicate Device**	**Remark**
1	510(k) Number	K253068	K061492	--
2	510(k) Holder	CMT HEALTH PTE. LTD.	TYCO HEALTHCARE	Same
3	Trade Name	Profoject™ Safelock Disposable Insulin Syringe	Kendall Monoject Magellan Insulin Safety Syringe	--
4	Common Name	syringe, antistick	syringe, antistick	Same
5	Regulation Name	Piston syringe	Piston syringe	Same
6	Product Code	MEG	MEG	Same

7	Regulation Number	21 CFR 880.5860	21 CFR 880.5860	Same
8	Review Panel	General Hospital	General Hospital	Same
9	Device Class	II	II	Same
10	Indications for use	The device is intended for the delivery of U-40 or U-100 insulin. The needle stick prevention feature of the device, once activated, guards against accidental needle-sticks.	The device is intended for the delivery of U-100 insulin. The needle stick prevention feature of the device, once activated, guards against accidental needle-sticks.	Different Note 1
11	Design Features	-Manually operated safety feature to prevent accidental needle sticks. -Graduation markings	-Manually operated safety feature to prevent accidental needle sticks. -Graduation markings	Same
12	Mechanism of Action	Mechanical delivery of U-40 and U-100 insulin. Needle-stick prevention feature is manually activated by the user by a finger-tip or thumb operation.	Mechanical delivery of U-100 insulin. Needle-stick prevention feature is manually activated by the user by a finger-tip or thumb operation.	Different Note 2
13	Components	Sterile Syringe Single lumen needle Safety shield/feature	Sterile Syringe Single lumen needle Safety shield/feature	Same
14	Prescription vs. OTC	Prescription Use Only	Prescription Use Only	Same
15	Sterile vs. Non-Sterile	Sterile	Sterile	Same
16	Sterilization Method	EO	Gamma Radiation	Different Note 3
17	Shelf life	5 years	5 years	Same
18	Single Use vs. Reusable	Single Use	Single Use	Same
19	Non-pyrogenic	Yes	Yes	Same
20	Needle Size	29G, 30G, 31G	29G, 30G	Different Note 4
21	Needle Length	1/2", 5/16", 3/8", 1/4"	1/2", 5/16"	
22	Wall Thickness	Regular Wall, Thin Wall	Regular Wall	
23	Lubricant	Polydimethylsiloxane	Silicone	Different Note 5
24	Needle Cap Color	U-40 Insulin: Red U-100 Insulin: Orange	Orange	Different Note 6
25	Device Materials (barrel and shield)	Polypropylene and Polypropylene	Polypropylene and Polypropylene	Same
Differences between proposed device and predicate device, reference device:				
Note 1: The proposed device and the predicate device have the same indications for use of insulin injection and the proposed device has another syringe type for U-40 insulin injection. The difference between U-40 insulin				

syringe and U-100 insulin syringe is the insulin concentration delivery, the U-40 insulin syringe has red needle cap for color marking in accordance with ISO 8537 to distinguish the insulin concentration. In addition, the tolerance on graduated capacity has been validated in accordance with ISO 8537. Therefore, the differences between U-40 insulin syringes and U-100 insulin syringes do not raise any new questions of safety and effectiveness.

Note 2:

The mechanism of action of the insulin syringes of the proposed device and predicate device is the same. The difference between U-40 insulin syringe and U-100 insulin syringe is the insulin concentration delivery, the U-40 insulin syringe has red needle cap for color marking in accordance with ISO 8537 to distinguish the insulin concentration.

Note 3:

Although the proposed device and the predicate device were sterilized differently, the proposed device was sterilized by EO to achieve a SAL rating of 10^{-6}, which is the same as the predicate device, and therefore does not raise new questions of safety and effectiveness when compared to the predicate device.

Note 4:

The proposed device's needle size, needle length and wall thickness are different from the predicate device. This difference does not affect intended use. The differences on wall thickness does not raise new questions of safety and effectiveness when compared to the predicate device. In addition, differences in wall thickness between the predicate and proposed device were addressed through ISO 8537 and ISO 9626 performance testing.

Note 5:

The material of lubricant is different between the proposed device and predicate device. This difference does not raise any new questions of safety and effectiveness when compared to the predicate device. The biocompatibility test of the proposed device was conducted to demonstrate that the proposed device met the biocompatibility requirements.

Note 6:

The insulin syringe needle cap colors are different among the proposed device and predicate device. The U-40 insulin syringe has red protective cap for color marking in accordance with ISO 8537 to distinguish the insulin concentration. In addition, biocompatibility on the needle caps was conducted and supports that this difference does not impact the safety and effectiveness of the device to claim substantially equivalent to the predicate device.

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 devices identified in the submission. Thus the subject devices are substantially equivalent to the predicate devices.