



September 25, 2026

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

Re: K261372
Trade/Device Name: Profoject™ LOR Syringe
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia conduction kit
Regulatory Class: Class II
Product Code: CAZ
Dated: August 21, 2026
Received: August 21, 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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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,

JAMES J. LEE -S

for Bradley Quinn

Assistant Director

DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices

OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K261372

Device Name

Profoject™ LOR Syringe

Indications for Use (Describe)

Profoject™ LOR Syringe is intended for use in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the Loss of Resistance technique, it will be filled with air and/or saline during use. The LOR Syringe is not intended for injection or aspiration. The syringe will be sold sterile individually packaged, and as part of a sterile kit. The intended patient population includes children, adolescents, and adults.

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:	K261372
Date:	April 27, 2026
Type of 510(k) Submission:	Traditional
Submitter:	CMT HEALTH PTE. LTD. 6001 BEACH ROAD, #19-13A, GOLDEN MILE TOWER, SINGAPORE 199589 Contact Person: Monica Ma E-mail: ra@cmthealth.com Tel: +65 6846 1379

2. Device Description

Trade Name:	Profoject™ LOR Syringe
Common Name:	Loss of Resistance Syringe
Regulation Name:	Anesthesia Conduction Kit
Product Code:	CAZ
Device Class:	II
Regulation Number:	21 CFR 868.5140
Review Panel:	Anesthesiology
Indications for use:	Profoject™ LOR Syringe is intended for use in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the Loss of Resistance technique, it will be filled with air and/or saline during use. The LOR Syringe is not intended for injection or aspiration. The syringe will be sold sterile individually packaged, and as part of a sterile kit. The intended patient population includes children, adolescents, and adults.
Device Description:	The Profoject™ LOR Syringe is available in two models: Model A and Model B. Model A is a syringe equipped with an NRFit slip or NRFit lock connector that complies with ISO 80369-6, while Model B is a syringe equipped with a Luer slip or Luer lock connector that complies with ISO 80369-7. Depending on the type of plunger assembly, Model B can be further subdivided into Model B1 and Model B2. Model A has only one type of plunger assembly. The product is offered in three volume sizes: 5 mL, 7 mL, and 10 mL. ● Model A: Available with NRFit lock or NRFit slip male connectors (compliant with ISO 80369-6). The type of plunger is one-piece plunger. ● Model B: Model B1: Available with Luer lock or Luer slip male connectors (compliant with ISO 80369-7); and the type of plunger is one-piece plunger. Model B2: Fitted with Luer slip male connector only (compliant with

	ISO 80369-7). The type of plunger is three-piece plunger. The devices are single-use and are supplied either sterile and individually packaged, or non-sterile and bulk-packed. The sterile devices are sterilized with ethylene oxide gas to achieve an SAL of 10^{-6} and are provided with a sterility maintenance package that maintains sterility throughout the shelf life. The non-sterile, bulk-packed syringes are supplied to anesthetic conduction kit manufacturers for incorporation into the kit and terminal sterilization.
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3. Predicate Device Identification

K061737 - LOSS OF RESISTANCE SYRINGE

4. Non-Clinical Test Conclusion

Non-clinical verification of the Profoject™ LOR Syringe 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:

4.1. Performance Testing

- 1) ISO 7886-1 Second edition 2017-05 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
- 2) ISO 80369-1 Second edition 2018-11 Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements
- 3) ISO 80369-6 First Edition 2016-03-15 Small bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications
- 4) ISO 80369-7 Second edition 2021-05 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
- 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) 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)]
- 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) USP - NF <788> Particulate Matter in Injections

- 14) USP - NF <85> Bacterial Endotoxin Testing
- 15) 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)]
- 16) ISTA 3A: 2018 Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less
- 17) USP - NF <788> Particulate Matter in Injections
- 18) Testing for Scale Marking Stability

4.2. Biocompatibility Testing

The biocompatibility evaluation for the Profoject™ LOR Syringe 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 device is classified as an externally communicating device.

- 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. Usability Testing

Simulated Clinical Study Report

6. Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data was not included in this submission.

7. Substantially Equivalent Comparison Conclusion

7.1. Comparison of Technology Characteristics

Table 1 Comparison of Technology Characteristics

Parameters		Proposed Device	Predicate Device	Remark
1	510(k) Number	K261372	K061737	/
2	510(k) Holder	CMT HEALTH PTE. LTD.	Robert Busse & Co., Inc.	/
3	Trade Name	Profoject™ LOR Syringe	LOSS OF RESISTANCE SYRINGE	/
4	Product Code	CAZ	CAZ	Same
5	Regulation Number	21CFR 868.5140	21 CFR 868.5140	

6	Review Panel	Anesthesiology	Anesthesiology	
7	Device Class	II	II	Same
8	Indications for use	The Profoject™ LOR Syringe is intended for use in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the loss of Resistance technique, it will be filled with air and/or saline during use. The loss of resistance syringe is not intended for injection or aspiration. The syringe will be sold sterile individually packaged, and as part of a sterile kit.	The Busse Loss of Resistance Syringe is intended for use in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the loss of Resistance technique, it will be filled with air and/or saline during use. The loss of Resistance Syringe is not intended for injection or aspiration. The syringe will be sold sterile individually packaged, and as part of a sterile kit.	Same
9	Overall design	Barrel; Plunger	Barrel; Plunger	Same
10	Single Use	Single Use	Single Use	Same
11	Priming Volume	5mL, 7mL, 10mL	10mL	Different See Note 1
12	Connectivity	ISO 80369-6 ISO 80369-7	ISO 80369-7	Different See Note 2
13	Materials	Model A Barrel: Polypropylene Plunger: Polypropylene, yellow color additive Plunger stopper: Silicone compound and Light blue color additive Model B1 Barrel: Polypropylene Plunger: Polypropylene, blue color additive Plunger stopper: Silicone compound and Light blue color additive Model B2 Barrel: Polypropylene Plunger: Polypropylene, white color additive and blue color additive Plunger stopper: Polyisoprene rubber	Plastic materials	Different See Note 3
14	Biocompatibility	Complies with ISO 10993-1	Complies with ISO	Same

			10993-1	
15	Sterile	Sterile or non-sterile	Sterile or non-sterile	Same
16	Sterile Method	EO Sterilized	EO Sterilized	Same
17	Sterilization	SAL=10 ⁻⁶	SAL=10 ⁻⁶	Same

7.2. Substantial Equivalence Discussion

Table 2 Substantial Equivalence Discussion

Discussion	Note 1 - Syringe Volume: The syringe volume of the proposed device differs from that of the predicate device. However, this difference is just in capacity. In clinical practice, physicians select the appropriate syringe specification based on individual patient conditions, and this difference does not affect the intended use. Furthermore, bench performance testing was conducted on the proposed device in accordance with ISO 7886-1, ISO 80369-7, and ISO 80369-6, and all results met the requirements of these standards. Therefore, this difference does not raise new questions of safety or effectiveness. Note 2 - Connectivity: The proposed device includes both ISO 80369-7 and ISO 80369-6 connectors, whereas Predicate Device includes only ISO 80369-7 connector. All connectors on the proposed device have been tested and conform to ISO 80369-6 and ISO 80369-7 standards, and labeling addresses misconnection risks. Therefore, this difference does not raise new questions of safety or effectiveness. Note 3 - Materials: The specific materials of the predicate devices are not publicly available. However, the proposed devices were tested, and the results demonstrated that they complied with the ISO 10993 series standards. Predicate devices are legally marketed and have been determined to meet equivalent biocompatibility requirements. Therefore, the lack of publicly available predicate material information does not raise different questions of safety and effectiveness. In addition, bench performance testing per ISO 7886-1, ISO 80369-7, and ISO 80369-6 was conducted on the proposed device, and all results met the standard requirements. Accordingly, the proposed device is substantially equivalent to the predicate devices.
Conclusion	The Profoject™ LOR Syringe is substantially equivalent to its predicate device. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.