April 2, 2025

Prosum Medical Limited
% Scott Zawko
Manager, Regulatory Affairs
Kymanox
430 Davis Dr
Ste #300
Morrisville, North Carolina 27560

Re: K250138
Trade/Device Name: Small Volume 0.2mL Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QNQ
Dated: January 15, 2025
Received: January 17, 2025

Dear Scott Zawko:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

for Rong Guo -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)*
K250138

Device Name
Small Volume 0.2mL Syringe

Indications for Use *(Describe)*
The Small Volume 0.2mL Syringe is intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1 Date Prepared

March 31, 2025

2 Submitter

Manufacturer:	Prosum Medical Limited
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Contact Person:	Yanshen Sun
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Email:	info@prosummedical.co.uk

3 Device

Trade name:	Small Volume 0.2mL Syringe
Common Name:	Syringe
Classification name:	Low Dead Space Piston Syringe
Regulation:	21 CFR 880.5860
Product code:	QNQ
Classification:	Class II

4 Predicate Device

Predicate device:	K210443, PLPT LDV Sterile Syringe

5 Device Description

The Small Volume 0.2mL Syringe is intended for manual, single use. It is a small volume 0.2 mL syringe. It is comprised of a PP barrel, ABS plunger, TPE plunger stopper, PP plunger shield and PP Luer protective cap. The device has a Luer lock connection type that enables connection to a hypodermic needle for liquid injection or withdrawal. The device has a plunger stopper to prevent any liquid residual from remaining in the syringe barrel, maximizing the efficiency of liquid usage. The feature is called Low Dead Space/Volume. The Luer protective cap serves to safeguard the small Luer connector from potential damage during transportation. Similarly, the plunger shield is utilized to ensure the small plunger remains undamaged during transportation. The Luer protective cap and the plunger shield are optional to be used. The device has been manufactured without any silicone oil.

The device has six models, each equipped with a 0.2 mL Luer lock syringe. Among these models, three include an additional feature for enhanced dosing technology (EDT), which comprises a colored reference line on the plunger surface to improve visibility. These include identifying markings to distinguish the EDT models from the regular 0.2 mL syringe.

Table 1. Device Models

No.	Syringe Volume (mL)	Luer type	Description
1	0.2	Luer Lock	Small Volume 0.2mL Syringe, Luer Lock, EDT
2	0.2	Luer Lock	Small Volume 0.2mL Syringe, Luer Lock, EDT, Luer protective cap
3	0.2	Luer Lock	Small Volume 0.2mL Syringe, Luer Lock, EDT, Luer protective cap, Plunger shield
4	0.2	Luer Lock	Small Volume 0.2mL Syringe, Luer Lock
5	0.2	Luer Lock	Small Volume 0.2mL Syringe, Luer Lock, Luer protective cap
6	0.2	Luer Lock	Small Volume 0.2mL Syringe, Luer Lock, Luer protective cap, Plunger shield

6 Indications for Use/Intended Use

The Small Volume 0.2mL Syringe is intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.

7 Technological Characteristics

The table below compares the technological characteristics of the subject device and those of the predicate device.

Table 2. Device Comparison

	Subject Device (Small Volume 0.2mL Syringe)	**Predicate Device (PLPT LDV (Low Dead Volume) Sterile Syringe, K210443)**	**Comments**
Indications for Use / Intended use	The Small Volume 0.2mL Syringe is intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.	The PLPT LDV (Low Dead Volume) sterile syringe is intended to be used for medical purposes to inject fluid into or withdraw fluid from the human body.	Same
Product Code	QNQ	QNQ	Same
Rx Only or OTC	Prescription Use Only	Prescription Use Only	Same

	Subject Device **(Small Volume 0.2mL Syringe)**	**Predicate Device** **(PLPT LDV (Low Dead Volume) Sterile Syringe, K210443)**	**Comments**
Mechanism of Action	Manual use	Manual use	Same
Components and Materials	- Barrel: PP - Plunger: ABS - Stopper: TPE - Luer protective Cap: PP - Plunger shield: PP	- Barrel: PP - Plunger: PP - Stopper: Rubber	See Comment #1 below
Syringe Volume	0.2 mL	1 mL	See Comment #2 below
Connection Type	Luer-lock	Luer-lock	Same
Sterilization	EO gas SAL: 10^{-6}	EO gas SAL: 10^{-6}	Same
Shelf-life	3 years	3 years	Same
Biocompatibility	Complies with ISO 10993-1 - Cytotoxicity - Irritation - Sensitization - Acute systemic toxicity - Hemocompatibility - Pyrogenicity	Complies with ISO 10993-1 - Cytotoxicity - Irritation - Sensitization - Acute systemic toxicity - Hemocompatibility - Pyrogenicity	Same
Syringe Performance Testing	Complies with the following standards - ISO 7886-1 - ISO 80369-7	Complies with the following standards - ISO 7886-1 - ISO 80369-7	Same
Dead Space Specification	≤ 0.0058 mL 95% confidence/ 95% reliability meets requirements	≤ 0.023 mL 95% confidence/ 95% reliability meets requirements	See Comment #2 below

Comment #1, Components and Materials: The proposed device features an additional Luer protective cap and a plunger shield that safeguard the luer connector and the plunger from potential damage during transportation. The Luer protective cap and plunger shield are discarded by the user prior to use and do not alter the mechanism of action or functionality of the proposed device in comparison to the predicate. Protection of the device through transportation has been demonstrated through packaging validation per ISO 11607. The proposed device utilizes different polymer materials for the components in comparison to the predicate device. The difference of materials has been addressed through demonstration of biocompatibility in accordance with the ISO 10993 standards.

Comment #2, Syringe Volume and Dead Space Specification: The proposed device features a lower syringe volume in comparison to the predicate device. In addition to the lower total syringe volume, a lower dead space volume is achieved. These differences have been assessed through syringe performance testing conducted in accordance with ISO 7886-1 that demonstrates that the proposed device meets all necessary requirements. The differences in syringe volume and dead volume specifications do not raise new questions of safety and effectiveness when compared to the predicate device.

8 Non-clinical testing

8.1 Performance testing

The proposed device was tested in compliance with ISO 7886-1:2017 for evaluating the overall non-clinical performance. In addition, Luer connector testing in compliance with ISO 80369-7:2016 and ISO 80369-20:2015 was conducted for evaluating the performance of connection to hypodermic needle. The performance and design testing results met the standards' requirements to demonstrate the device's substantial equivalence. Testing was conducted on unconditioned samples as well as samples aged according to ASTM F1980 and samples transit conditioned according to ASTM D4169-22.

8.2 Biocompatibility testing

The proposed device was tested in compliance with FDA Guidance *Use of International Standard ISO 10993-1 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process*", as an Externally Communicating Device, Blood Path Indirect, Limited Contact (< 24 h).

The following endpoints were tested in accordance with ISO 10993-1: cytotoxicity, irritation, sensitization, acute systemic toxicity, hemocompatibility, and pyrogenicity. Particulate matter was tested in compliance with USP <788> and bacterial endotoxins were tested in compliance with USP <85> and met the acceptance criteria.

8.3 Sterility, packaging, and shelf-life

The sterilization process of the proposed device has been validated in compliance with ISO 11135. The EO and ECH residuals do not exceed the limits according to ISO 10993-7.

The shelf-life verification was conducted under accelerated aging conditions in compliance with ASTM F1980-16 to demonstrate device functionality through the claimed shelf-life of 3 years.

Performance testing, package integrity testing, sterility testing, and particulate testing were conducted on samples accelerated aged to 3 years. Real time testing will be conducted to confirm device functionality through a shelf-life of 3 years.

Package integrity testing under simulated shipping conditions was conducted to satisfy the requirements in ASTM D4169-22 *Standard Practice for Performance Testing of Shipping Containers and Systems*. Simulated shipping conditions consisted of Distribution Cycle 13, Assurance Level 2. All packaging was deemed acceptable for protection of product and sterility maintenance.

Sterile barrier testing was conducted in compliance with the following FDA recognized consensus standards.

- ASTM F88/F88-15 *Standard Test Method for Seal Strength of Flexible Barrier Materials*
- ASTM F1929-15 *Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration*
- USP <71> *Sterility Tests*

A shelf life of 3 years is validated in accordance with ISO 11607-1 and ISO 11607-2.

9 Clinical testing

Not applicable for this submission.

10 Conclusion

The differences between the predicate and the proposed device do not raise any new or different questions of safety or effectiveness. The proposed device is substantially equivalent to the predicate device with respect to indications for use and technological characteristics.