December 17, 2025

Duopross Meditech Corporate
% Eva Li
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave.
Shanghai, 200122
China

Re: K252518
Trade/Device Name: DuoprossTM Smart Cap (Type I)
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: November 21, 2025
Received: November 21, 2025

Dear Eva Li:

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,

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)*
K252518

Device Name
DuoprossTM Smart Cap (Type I)

Indications for Use *(Describe)*
Smart Caps are indicated for use as sterile tip caps with tamper-evident function for luer-lock syringes. The use time of the Smart cap should be ≤ 24 hours.

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. Basic information

Date prepared:	Dec 17, 2025
Submitter:	Duopross Meditech Corporate
Address:	154 Marine St, Farmingdale N.Y. 11735
Manufacturing Company:	Duopross Meditech (Kunshan) Co., Ltd.
Manufacturing Address:	Taihong Road Yushan Town Wusong Jiang, Kunshan Jiangsu, CN 215300
Contact person:	Alan Yang
Telephone Number:	+86 155 4242 0089
Email Address:	hongkang.yang_alan@dpsmeditech.com

Trade Name:	DuoprossTM Smart Cap (Type I)
Device 510(k):	K252518
Device Common Name:	Tamper Evident Cap
Regulation Number:	21 CFR 880.5860
Regulation Name:	Piston syringe
Product Class:	II
Product Panel:	General Hospital
Product Code:	FMF

Predicate Device Name:	TrueCare Biomedix Tamper Evident Cap
Predicate Device 510(k):	K210818
Device Common Name:	Tamper Evident Cap
Regulation Number:	21 CFR 880.5860
Regulation Name:	Piston syringe
Product Class:	II
Product Panel:	General Hospital
Product Code:	FMF

2. Device Description

The Smart Cap is a tamper-evident syringe cap with a clear indication of cap removal to ensure sterility and reduce the risk of medical fluids being compromised accidentally or intentionally. Its assembly includes an outer cover, an inner cap and an inner ring. It is made of acrylonitrile butadiene styrene (ABS) and polypropylene (PP) and is sterilized by ethylene oxide.

3. Indication for use

Smart Caps are indicated for use as sterile tip caps with tamper-evident function for luer-lock syringes. The use time of the Smart cap should be ≤ 24 hours.

4. Comparison of Technological Characteristics and Basis for

Substantial Equivalence

Item	Predicate Device	Subject device	Comparison
Device Name	TrueCare Biomedix Tamper Evident Cap	Duopross™ Smart Cap	N/A
Indication for use	Tamper Evident Caps are indicated for use as a sterile tamper evident cap for IV syringes.	Smart Caps are indicated for use as sterile tip caps with tamper-evident function for luer-lock syringes. The use time of the Smart cap should be ⩽ 24 hours.	Difference #1
Fundamental Scientific Technology	Female luer lock cap with clear tamper evident outer shell/housing	Female luer lock cap with clear tamper evident outer shell/housing	same
Sterility	Sterile EO (10^-6)	Sterile EO (10^-6)	same
Number of Uses	Single Use, Rx only	Single Use, Rx only	same
Connection	Female luer lock	Female luer lock	same
Tamper Evidence Design Feature	Clear outer shell/housing that separates from the cap upon opening	Clear outer shell/housing that separates from the cap upon opening	same
Materials	Indirect patient contacting: PP 1024 polypropylene with red color additive Non-patient contacting: Acrylonitrile Butadiene Styrene	Indirect patient contacting: Acrylonitrile Butadiene Styrene with blue color additive Non-patient contacting: polypropylene	Difference #2
Biocompatibility Contact / Duration	Indirect blood contact, limited duration.	Indirect blood contact, limited duration.	same

Discussion of Technological differences:
Difference #1: The intended use of Smart Cap is similar to intended use of the predicate. Both are indicated for use as tamper evident caps for syringes. Both devices are Rx Only. This difference does not raise any new or different questions of safety or effectiveness when compared to the predicate device.
Difference #2: While the cap material is different, the subject device meets the requirements of ISO 10993-1. This difference does not raise any new or different questions of safety or effectiveness when compared to the predicate device.

5. Non-clinical bench testing

Bench performance

The testing was conducted as part of the Design Control process for the TEC product family to keep current with the latest ISO standard, 80369. For this product line, the appli

cable standards are ISO 80369-7, "Small-
bore connectors for liquids and gases in healthcare applications – Part 7 Connectors for intravascular or hypodermic applications"

Biocompatibility

In accordance with ISO 10993-1, the device is classified as Limited duration, externally communicating device, Blood Path Indirect (<24hours).

Sterility

A sterilization validation was conducted to ensure a Sterility Assurance Level (SAL) of 10^{-6} using the overkill method in compliance with ISO 11135 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 residual testing was completed for the subject device per ISO 10993-7 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals and the devices met the limits of < 4mg/device and < 9mg/device, respectively.
The sterile subject devices were evaluated for the potential to produce a pyrogenic response. The Limulus Amebocyte Lysate (LAL) test was used to test for Bacterial Endotoxins as part of process validations, and the devices met the limits of < 20 EU/device. Additionally, material-mediated pyrogen testing conducted as part of the biocompatibility testing conducted in support of this submission.

The subject device is currently labeled with a 3-year shelf life based on shelf life verification testing. Packaging system characteristics and integrity testing was conducted in accordance with the following standards:
• ISO 11607-1 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
• ISO 11607-2 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
• ASTM F1886 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
• ASTM F1929 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
• ASTM F88/F88M Standard Test Method for Seal Strength of Flexible Barrier Materials
• ASTM D4169 Standard Practice for Performance Testing of Shipping Containers and Systems
• ASTM F1980 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

6. Conclusions

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Duopross™ Smart Cap is substantially equivalent to the TrueCare Biomedix Tamper Evident Cap under K210818 with respect to the

indications for use, target populations, treatment method, and technological characteristics.