

K252518 Duopross™ Smart Cap (Type I)Dec 17, 2025
128 days to decisionK252518 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k252518/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Aug 11, 2025
Decision date	Dec 17, 2025
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Duopross Meditech Corporate
Location	Farmingdale, NY, US
Contact	Vincent Fu
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Shanghai SUNGO Management Consulting Co., Ltd.
Contact	Eva Li

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252518/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026