FDA 510(k) Premarket Notification

K252518 DuoprossTM Smart Cap (Type I)

CLEARED

Dec 17, 2025
128 days to decision

K252518 · 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