

K250262 GO-PEN®Apr 24, 2025
85 days to decisionK250262 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k250262/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Jan 29, 2025
Decision date	Apr 24, 2025
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Go-Pen Aps
Location	Kongens Lyngby, DK
Contact	Ole Nielsen
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Veranex
Contact	Paige Sutton-Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250262/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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