FDA 510(k) Premarket Notification

K250262 GO-PEN®

CLEARED

Apr 24, 2025
85 days to decision

K250262 · 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