FDA 510(k) Premarket Notification

K250138 Small Volume 0.2mL Syringe

CLEARED

Apr 2, 2025
75 days to decision

K250138 · Product code: **QNQ** · General Hospital
Source: https://www.510kdatabase.net/k250138/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Low Dead Space Piston Syringe (QNQ)
Date received	Jan 17, 2025
Decision date	Apr 2, 2025
Days to decision	75 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Prosum Medical Limited**
Location	Uxbridge, GB
Contact	Yanshen Sun
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Kymanox**
Contact	Scott Zawko

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