FDA 510(k) Premarket Notification

K240355 FROG (Filter Removal of Glass)

CLEARED

Apr 18, 2025
438 days to decision

K240355 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k240355/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Feb 5, 2024
Decision date	Apr 18, 2025
Days to decision	438 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Carrtech Corp**
Location	Frederick, MD, US
Contact	Sue Carr
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Gilero**
Contact	Ann Metz

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