

K240355 FROG (Filter Removal of Glass)Apr 18, 2025
438 days to decisionK240355 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240355/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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