

K213846 Q2 Blood Administration SetsJun 5, 2022
177 days to decisionK213846 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k213846/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Dec 10, 2021
Decision date	Jun 5, 2022
Days to decision	177 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Quest Medical, Inc.
Location	Walker, MI, US
Contact	Tosan Eweka
510(k) history	39 submissions · 39 cleared · 1980-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213846/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026