FDA 510(k) Premarket Notification

K213846 Q2 Blood Administration Sets

CLEARED

Jun 5, 2022
177 days to decision

K213846 · 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