FDA 510(k) Premarket Notification

K213588 Q2 IV Administration Sets

CLEARED

Jun 2, 2022
202 days to decision

K213588 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k213588/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Nov 12, 2021
Decision date	Jun 2, 2022
Days to decision	202 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