FDA 510(k) Premarket Notification

K202672 Precision Delivery Infusion Set

CLEARED

Jan 21, 2021
128 days to decision

K202672 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k202672/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Sep 15, 2020
Decision date	Jan 21, 2021
Days to decision	128 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