FDA 510(k) Premarket Notification

K241058 Lyka® PORT Needle Free Access Device (4170Y)

CLEARED

Dec 18, 2024
244 days to decision

K241058 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k241058/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Apr 18, 2024
Decision date	Dec 18, 2024
Days to decision	244 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Quest Medical, Inc.**
Location	Walker, MI, US
Contact	Stephanie Edugie Ajayi
510(k) history	39 submissions · 39 cleared · 1980-2024