

**K241058 Lyka® PORT Needle Free Access Device (4170Y)**Dec 18, 2024  
244 days to decisionK241058 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k241058/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241058/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026