

**K211218 BD Alaris System with Guardrails Suite MX v12.1.2**Jul 21, 2023  
819 days to decisionK211218 · Product code: **FRN** · General Hospital  
Source: <https://www.510kdatabase.net/k211218/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Apr 23, 2021
Decision date	Jul 21, 2023
Days to decision	819 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Carefusion 303, Inc.</b>
Location	San Diego, CA, US
Contact	Laurie Cartwright
510(k) history	7 submissions · 7 cleared · 2011-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211218/> 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 26, 2026