

K243855 BD Alaris Infusion System with Guardrails Suite MXApr 25, 2025
130 days to decisionK243855 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k243855/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Dec 16, 2024
Decision date	Apr 25, 2025
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Carefusion 303, Inc.
Location	San Diego, CA, US
Contact	Darin Oppenheimer
510(k) history	7 submissions · 7 cleared · 2011-2025

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