

**K251636 Spectrum IQ Infusion System with Dose IQ Safety Software (3570009)**Jul 28, 2025  
60 days to decisionK251636 · Product code: **FRN** · General Hospital  
Source: <https://www.510kdatabase.net/k251636/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	May 29, 2025
Decision date	Jul 28, 2025
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Baxter Healthcare Corporation</b>
Location	Round Lake, IL, US
Contact	Jessica Andreshak
510(k) history	61 submissions · 60 cleared · 2004-2025

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251636/> 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