

# K251640 SIGMA Spectrum Infusion Pump with Master Drug Library

Jul 28, 2025  
60 days to decisionK251640 · Product code: **FRN** · General Hospital  
Source: <https://www.510kdatabase.net/k251640/>

## 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/k251640/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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