

**K242660 Curlin 8000 Ambulatory Infusion System**Oct 3, 2024  
29 days to decisionK242660 · Product code: **FRN** · General Hospital  
Source: <https://www.510kdatabase.net/k242660/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Infusion (FRN)
Date received	Sep 4, 2024
Decision date	Oct 3, 2024
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Enterprise Solution (ES) Software; Curlin 380-series Administration Sets

**APPLICANT**

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Company	<b>Zevex, Inc.</b>
Location	Salt Lake City, UT, US
Contact	Santosh Bhagat
510(k) history	5 submissions · 5 cleared · 2001-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242660/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026