

**K234027 embecta Insulin Delivery System**Aug 30, 2024  
254 days to decisionK234027 · Product code: **QFG** · Chemistry  
Source: <https://www.510kdatabase.net/k234027/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alternate Controller Enabled Insulin Infusion Pump (QFG)
Date received	Dec 20, 2023
Decision date	Aug 30, 2024
Days to decision	254 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Embecta Medical I, LLC</b>
Location	Andover, MA, US
Contact	Andrew Harrell
510(k) history	1 submissions · 1 cleared · 2024-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k234027/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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