

**K161667 Sapphire Infusion Pump**Mar 27, 2017  
284 days to decisionK161667 · Product code: **FRN** · General Hospital  
Source: <https://www.510kdatabase.net/k161667/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Jun 16, 2016
Decision date	Mar 27, 2017
Days to decision	284 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Q Core Medical , Ltd.</b>
Location	Gaithersburg, MD, US
Contact	Shimon Vaknin
510(k) history	5 submissions · 5 cleared · 2013-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161667/> 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 June 28, 2026