

**K171346 Sapphire Sets**Aug 25, 2017  
109 days to decisionK171346 · Product code: **MRZ** · General Hospital  
Source: <https://www.510kdatabase.net/k171346/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Pump, Infusion (MRZ)
Date received	May 8, 2017
Decision date	Aug 25, 2017
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Icu Medical</b>
Location	Lake Forest, IL, US
Contact	Andrea Doyle
510(k) history	5 submissions · 5 cleared · 2017-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171346/> 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 24, 2026