

**K223607 Plum Duo™ Infusion System**Aug 24, 2023  
265 days to decisionK223607 · Product code: **FRN** · General HospitalSource: <https://www.510kdatabase.net/k223607/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Dec 2, 2022
Decision date	Aug 24, 2023
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Icu Medical, Inc.</b>
Location	Walker, MI, US
Contact	Yuliya Matlin
510(k) history	66 submissions · 65 cleared · 1984-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223607/> 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 14, 2026