

K242115 Plum Duo™ Precision IV PumpApr 2, 2025
257 days to decisionK242115 · Product code: **FRN** · General HospitalSource: <https://www.510kdatabase.net/k242115/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Jul 19, 2024
Decision date	Apr 2, 2025
Days to decision	257 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242115/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026