

K243985 Rio™ Drug Reconstitution Transfer DeviceJan 22, 2025
30 days to decisionK243985 · Product code: LHI · General Hospital
Source: <https://www.510kdatabase.net/k243985/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, I.v. Fluid Transfer (LHI)
Date received	Dec 23, 2024
Decision date	Jan 22, 2025
Days to decision	30 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243985/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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