

**K192154 Rio Vial-to-Bag Drug Reconstitution Device**Apr 20, 2020  
255 days to decisionK192154 · Product code: **LHI** · General Hospital  
Source: <https://www.510kdatabase.net/k192154/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, I.v. Fluid Transfer (LHI)
Date received	Aug 9, 2019
Decision date	Apr 20, 2020
Days to decision	255 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Icu Medical</b>
Location	Lake Forest, IL, US
Contact	Sheila Antonio
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/k192154/> 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