

**K203256 Imbio RV/LV Software**Mar 9, 2021  
125 days to decisionK203256 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k203256/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Nov 4, 2020
Decision date	Mar 9, 2021
Days to decision	125 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Imbio, LLC</b>
Location	Minneapolis, MN, US
Contact	William McLain
510(k) history	3 submissions · 3 cleared · 2014-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203256/> 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 27, 2026