

**K123753 IMDX VANR FOR ABBOTT M2000**Jul 17, 2013  
223 days to decisionK123753 · Product code: **NIJ** · Microbiology  
Source: <https://www.510kdatabase.net/k123753/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Genotypic Detection, Resistant Markers, Enterococcus Species (NIJ)
Date received	Dec 6, 2012
Decision date	Jul 17, 2013
Days to decision	223 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Intelligent Medical Devices, Inc.</b>
Location	Beverly, MA, US
Contact	FRAN WHITE
510(k) history	4 submissions · 4 cleared · 2013-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123753/> 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