

**K113319 ROTOR-GENE Q MDX**Feb 6, 2012  
88 days to decisionK113319 · Product code: **OOI** · Microbiology  
Source: <https://www.510kdatabase.net/k113319/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Real Time Nucleic Acid Amplification System (OOI)
Date received	Nov 10, 2011
Decision date	Feb 6, 2012
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>QIAGEN GmbH</b>
Location	Hilden, DE
Contact	MELISSA MAHALL
510(k) history	13 submissions · 13 cleared · 2012-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113319/> 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