

**K171511 RIDA GENE Norovirus GI/GII**Aug 21, 2017  
89 days to decisionK171511 · Product code: **PIQ** · Microbiology  
Source: <https://www.510kdatabase.net/k171511/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagents For Detection Of Norovirus Nucleic Acid (PIQ)
Date received	May 24, 2017
Decision date	Aug 21, 2017
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>R-Biopharm AG</b>
Location	East Stroudsburg, PA, US
Contact	Andreas Simons
510(k) history	2 submissions · 1 cleared · 2011-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171511/> 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