

**K173492 MRDx BCR-ABL Test, MRDx BCR-ABL Test Software**Dec 22, 2017  
39 days to decisionK173492 · Product code: **OYX** · Pathology  
Source: <https://www.510kdatabase.net/k173492/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - SD
Submission type	Traditional
Device classification	Bcr/abl1 Monitoring Test (OYX)
Date received	Nov 13, 2017
Decision date	Dec 22, 2017
Days to decision	39 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>MolecularMD Corporation</b>
Location	Portland, OR, US
Contact	Kevin Hawkins
510(k) history	1 submissions · 0 cleared · 2017-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173492/> 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 13, 2026