

**K150031 hemoFISH Masterpanel**Oct 1, 2015  
266 days to decisionK150031 · Product code: **JSS** · Microbiology  
Source: <https://www.510kdatabase.net/k150031/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Identification, Enterobacteriaceae (JSS)
Date received	Jan 8, 2015
Decision date	Oct 1, 2015
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Miacom Diagnostics GmbH</b>
Location	Dusseldorf, DE
Contact	EVE BLOMEKE
510(k) history	1 submissions · 1 cleared · 2015-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k150031/> 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 June 3, 2026