

**K121991 ENTEROCOCCUS QUICKFISH BC**Jan 7, 2013  
185 days to decisionK121991 · Product code: **OAH** · Microbiology  
Source: <https://www.510kdatabase.net/k121991/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fish (fluorescent In Situ Hybridization) Kit, Protein Nucleic Acid, Enterococcus Faecalis (OAH)
Date received	Jul 6, 2012
Decision date	Jan 7, 2013
Days to decision	185 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Advandx, Inc.</b>
Location	Canton, MA, US
Contact	BENJAMIN S CRYSTAL
510(k) history	21 submissions · 21 cleared · 2006-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121991/> 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 6, 2026