

**K081433 EK/P. AERUGINOSA PNA FISH**Mar 26, 2009  
309 days to decisionK081433 · Product code: **JSS** · Microbiology  
Source: <https://www.510kdatabase.net/k081433/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Identification, Enterobacteriaceae (JSS)
Date received	May 21, 2008
Decision date	Mar 26, 2009
Days to decision	309 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Advandx, Inc.</b>
Location	Canton, MA, US
Contact	HENRIK STENDER
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/k081433/> 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