

**K140619 MECA XPRESSFISH**

Oct 10, 2014  
213 days to decision

K140619 · Product code: **MYI** · Microbiology  
Source: <https://www.510kdatabase.net/k140619/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Genotypic Detection, Resistant Markers, Staphylococcus Colonies (MYI)
Date received	Mar 11, 2014
Decision date	Oct 10, 2014
Days to decision	213 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Advandx, Inc.</b>
Location	Canton, MA, US
Contact	RON EISENWINTER
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/k140619/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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