

**K083074 AVANDX E. FAECALIS/OE PNA FISH CULTURE IDENTIFICATION KIT**Jul 24, 2009  
282 days to decisionK083074 · Product code: **OAH** · Microbiology  
Source: <https://www.510kdatabase.net/k083074/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fish (fluorescent In Situ Hybridization) Kit, Protein Nucleic Acid, Enterococcus Faecalis (OAH)
Date received	Oct 15, 2008
Decision date	Jul 24, 2009
Days to decision	282 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083074/>; Data sourced from FDA 510(k) public records (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