

K082612 GBS PNA FISHMay 5, 2009
238 days to decisionK082612 · Product code: **OAH** · Microbiology
Source: <https://www.510kdatabase.net/k082612/>**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	Sep 9, 2008
Decision date	May 5, 2009
Days to decision	238 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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