

K063127 ENTEROCOCCUS FAECALIS PNA FISHDec 22, 2006
70 days to decisionK063127 · Product code: **OAH** · Microbiology
Source: <https://www.510kdatabase.net/k063127/>**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 13, 2006
Decision date	Dec 22, 2006
Days to decision	70 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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