

K081309 E.COLI/P. AERUGINOSA PNA FISHDec 19, 2008
224 days to decisionK081309 · Product code: **JSS** · Microbiology
Source: <https://www.510kdatabase.net/k081309/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Identification, Enterobacteriaceae (JSS)
Date received	May 9, 2008
Decision date	Dec 19, 2008
Days to decision	224 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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