

K082068 E. COLI PNA FISHJun 25, 2009
338 days to decisionK082068 · Product code: **JSS** · Microbiology
Source: <https://www.510kdatabase.net/k082068/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Identification, Enterobacteriaceae (JSS)
Date received	Jul 22, 2008
Decision date	Jun 25, 2009
Days to decision	338 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k082068/> 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. - Generated June 6, 2026