

K092166 S. AUREUS/CNS PNA FISH, MODEL KT005Nov 23, 2009
125 days to decisionK092166 · Product code: **NXX** · Microbiology
Source: <https://www.510kdatabase.net/k092166/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fish (fluorescent In Situ Hybridization) Kit, Protein Nucleic Acid, Rna, Staphylococcus Aureus (NXX)
Date received	Jul 21, 2009
Decision date	Nov 23, 2009
Days to decision	125 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092166/> 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