

K091827 S. AUREUS PNA FISHAug 18, 2009
60 days to decisionK091827 · Product code: **NXX** · Microbiology
Source: <https://www.510kdatabase.net/k091827/>**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	Jun 19, 2009
Decision date	Aug 18, 2009
Days to decision	60 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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