

K113371 STAPHYLOCOCCUS QUICKFISH BCApr 3, 2012
139 days to decisionK113371 · Product code: **NXX** · Microbiology
Source: <https://www.510kdatabase.net/k113371/>**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	Nov 16, 2011
Decision date	Apr 3, 2012
Days to decision	139 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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