

K142721 cobas MRSA/SA TestDec 17, 2014
85 days to decisionK142721 · Product code: **NQX** · Microbiology
Source: <https://www.510kdatabase.net/k142721/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nucleic Acid Amplification Test, Dna, Methicillin Resistant Staphylococcus Aureus, Direct Specimen (NQX)
Date received	Sep 23, 2014
Decision date	Dec 17, 2014
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Molecular Systems, Inc.
Location	Somerville, NJ, US
Contact	Wilk von Gustedt
510(k) history	51 submissions · 48 cleared · 1993-2026

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