

K093346 BD GENE OHM MRSA ACP ASSAYDec 15, 2009
50 days to decisionK093346 · Product code: **NQX** · Microbiology
Source: <https://www.510kdatabase.net/k093346/>**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	Oct 26, 2009
Decision date	Dec 15, 2009
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bd Diagnostics (Geneohm Sciences, Inc.)
Location	San Diego, CA, US
Contact	RAYMOND BOULE
510(k) history	2 submissions · 2 cleared · 2008-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k093346/> 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 21, 2026