

K120138 BD MAX MRSA ASSAY, BD MAX INSTRUMENTJul 5, 2012
170 days to decisionK120138 · Product code: **NQX** · Microbiology
Source: <https://www.510kdatabase.net/k120138/>**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	Jan 17, 2012
Decision date	Jul 5, 2012
Days to decision	170 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bd Diagnostics (Geneohm Sciences Canada, Inc)
Location	San Diego, CA, US
Contact	RAYMOND J BOULE
510(k) history	2 submissions · 2 cleared · 2007-2012

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