

**K071026 BD GENE OHM STAPH SR ASSAY**Dec 20, 2007  
253 days to decisionK071026 · Product code: **NQX** · Microbiology  
Source: <https://www.510kdatabase.net/k071026/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nucleic Acid Amplification Test, Dna, Methicillin Resistant Staphylococcus Aureus, Direct Specimen (NQX)
Date received	Apr 11, 2007
Decision date	Dec 20, 2007
Days to decision	253 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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