

K132822 BD MAX STAPHSR ASSAY, INSTRUMENT

Nov 26, 2013
78 days to decision

K132822 · Product code: **NQX** · Microbiology
Source: <https://www.510kdatabase.net/k132822/>

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 9, 2013
Decision date	Nov 26, 2013
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Geneohm Sciences Canada, Inc. (Bd Diagnostics)
Location	Quebec, CA
Contact	PATRICIA DIONNE
510(k) history	4 submissions · 3 cleared · 2013-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k132822/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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