

K133605 BD MAX MRSA XT, BD MAX INSTRUMENTDec 20, 2013
25 days to decisionK133605 · Product code: **NQX** · Microbiology
Source: <https://www.510kdatabase.net/k133605/>**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 | Nov 25, 2013 |
| Decision date | Dec 20, 2013 |
| Days to decision | 25 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Geneohm Sciences Canada, Inc. |
| Location | Baldwin, MD, US |
| Contact | PATRICIA DIONNE |
| 510(k) history | 2 submissions · 2 cleared · 2006-2013 |

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