FDA 510(k) Premarket Notification

CLEARED

K093346 BD GENEOHM MRSA ACP ASSAY

Dec 15, 2009
50 days to decision

K093346 · 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