

K843827 COBAS REAGENTS FOR GENTAMICIN & CALIBRATFeb 1, 1985
126 days to decisionK843827 · Product code: **LCQ** · Toxicology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescent Immunoassay Gentamicin (LCQ)
Date received	Sep 28, 1984
Decision date	Feb 1, 1985
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	Roche Diagnostic Systems, Inc.
Location	Mchenry, IL, US
510(k) history	296 submissions · 296 cleared · 1983-1999

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