

K962819 GENTAMICIN FLEX REAGENT CARTRIDGESep 13, 1996
56 days to decisionK962819 · Product code: **LCD** · Toxicology
Source: <https://www.510kdatabase.net/k962819/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Gentamicin (LCD)
Date received	Jul 19, 1996
Decision date	Sep 13, 1996
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dade Intl., Inc.
Location	Deerfield, IL, US
Contact	CAROLYN K GEORGE
510(k) history	30 submissions · 30 cleared · 1995-1998

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