

K953020 ACS GENTAMICINAug 2, 1995
34 days to decisionK953020 · Product code: **LCD** · Toxicology
Source: <https://www.510kdatabase.net/k953020/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Gentamicin (LCD)
Date received	Jun 29, 1995
Decision date	Aug 2, 1995
Days to decision	34 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ciba Corning Diagnostics Corp.
Location	East Walpole, MA, US
Contact	STEVEN R RAKITIN
510(k) history	125 submissions · 125 cleared · 1986-1996

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