

K020704 ROCHE ONLINE GENTAMICINJul 12, 2002
130 days to decisionK020704 · Product code: **LCD** · Toxicology
Source: <https://www.510kdatabase.net/k020704/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Gentamicin (LCD)
Date received	Mar 4, 2002
Decision date	Jul 12, 2002
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	MIKE FLIS
510(k) history	264 submissions · 263 cleared · 1999-2013

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