

K003846 ACCU-CHEK INFORM METERMar 19, 2001
97 days to decisionK003846 · Product code: **LFR** · Chemistry
Source: <https://www.510kdatabase.net/k003846/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Dehydrogenase, Glucose (LFR)
Date received	Dec 12, 2000
Decision date	Mar 19, 2001
Days to decision	97 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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