

K050872 ACCU-CHEK INTEGRA SYSTEMMay 2, 2005
26 days to decisionK050872 · Product code: **LFR** · Chemistry
Source: <https://www.510kdatabase.net/k050872/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Glucose Dehydrogenase, Glucose (LFR)
Date received	Apr 6, 2005
Decision date	May 2, 2005
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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