

K061048 COBAS INTEGRA GLUCOSE HK GEN. 3 TEST SYSTEMMay 17, 2006
30 days to decisionK061048 · Product code: **CFR** · Chemistry
Source: <https://www.510kdatabase.net/k061048/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Hexokinase, Glucose (CFR)
Date received	Apr 17, 2006
Decision date	May 17, 2006
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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