

K953847 ROCHE REAGENT FOR GLUCOSEFeb 13, 1996
181 days to decisionK953847 · Product code: **CFR** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hexokinase, Glucose (CFR)
Date received	Aug 16, 1995
Decision date	Feb 13, 1996
Days to decision	181 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Roche Diagnostic Systems, Inc.
Location	Mchenry, IL, US
Contact	MARIA FEIJOO
510(k) history	296 submissions · 296 cleared · 1983-1999

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