

K963535 SIGMA DIAGNOSTICS GLUCOSE REAGENTJan 17, 1997
135 days to decisionK963535 · Product code: **CGA** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Sep 4, 1996
Decision date	Jan 17, 1997
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sigma Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	WILLIAM R GILBERT
510(k) history	164 submissions · 164 cleared · 1984-2002

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