

K971145 GLUCOSITE TEST SYSTEMSep 17, 1997
173 days to decisionK971145 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k971145/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Mar 28, 1997
Decision date	Sep 17, 1997
Days to decision	173 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gds Technology, LLC
Location	Elkhart, IN, US
Contact	JOHN W SWATOSH
510(k) history	7 submissions · 7 cleared · 1988-2000

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