

K014139 DIABETES ASSISTANT SOFTWAREMar 21, 2002
94 days to decisionK014139 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k014139/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Dec 17, 2001
Decision date	Mar 21, 2002
Days to decision	94 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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