

K001907 CAMIT DIABETES MANAGEMENT SOFTWARESep 5, 2000
75 days to decisionK001907 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k001907/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Jun 22, 2000
Decision date	Sep 5, 2000
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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