

K821091 ACCUCHEK BG.May 14, 1982
25 days to decisionK821091 · Product code: **CGA** · Hematology
Source: <https://www.510kdatabase.net/k821091/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Apr 19, 1982
Decision date	May 14, 1982
Days to decision	25 days
Third-party review	No

APPLICANT

Company	Biodynamics Corp.
Location	Walker, MI, US
510(k) history	21 submissions · 21 cleared · 1980-2006

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Device record: <https://www.510kdatabase.net/k821091/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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