FDA 510(k) Premarket Notification

# K820465 CHEMSTRIP UG

K820465 · Product code: **CGA** · Chemistry
Source: https://www.510kdatabase.net/k820465/

**CLEARED**

Mar 11, 1982
17 days to decision

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Glucose Oxidase, Glucose (CGA) |
| Date received | Feb 22, 1982 |
| Decision date | Mar 11, 1982 |
| Days to decision | 17 days |
| Third-party review | No |

## APPLICANT

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

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k820465/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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