

K963544 SUPREME II METERFeb 20, 1997
169 days to decisionK963544 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k963544/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Glucose Oxidase, Glucose (CGA) |
| Date received | Sep 4, 1996 |
| Decision date | Feb 20, 1997 |
| Days to decision | 169 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Chronimed, Inc. |
| Location | Eden Prairie, MN, US |
| Contact | JEFFREY P HEATON |
| 510(k) history | 5 submissions · 5 cleared · 1997-2001 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k963544/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026