

**K061528 SELF-CHECK GLUCO**Sep 22, 2006  
112 days to decisionK061528 · Product code: **CGA** · Chemistry  
Source: <https://www.510kdatabase.net/k061528/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Glucose Oxidase, Glucose (CGA)     |
| Date received         | Jun 2, 2006                        |
| Decision date         | Sep 22, 2006                       |
| Days to decision      | 112 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|--|
| Company        | <b>Card Guard Scientific Survival , Ltd.</b> |
| Location       | Israel, IL                                   |
| Contact        | ALEX GONOROVSKY                              |
| 510(k) history | 49 submissions · 49 cleared · 1988-2011      |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061528/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026