

**K113547 GAL-1E BLOOD GLUCOSE MONITORING SYSTEM  
GAL-1E BLOOD GLUCOSE TEST STRIPS GAL-1E MULTI  
BLOOD GLUCOSE MONITORING SYSTEM GAL**Mar 28, 2012  
118 days to decisionK113547 · Product code: **CGA** · Chemistry  
Source: <https://www.510kdatabase.net/k113547/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Glucose Oxidase, Glucose (CGA)     |
| Date received         | Dec 1, 2011                        |
| Decision date         | Mar 28, 2012                       |
| Days to decision      | 118 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Apex BioTechnology Corp.</b>         |
| Location       | Plymouth, MN, US                        |
| Contact        | HSUE-MEI LEE                            |
| 510(k) history | 35 submissions · 35 cleared · 2001-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113547/> 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 June 15, 2026