

**K102816 GAL-1C BLOOD GLUCOSE MONITORING SYSTEM,  
GAL-1C TEST STRIPS**Sep 15, 2011  
352 days to decisionK102816 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k102816/>**SUBMISSION DETAILS**

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|                       |                                                     |
|-----------------------|-----------------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)                  |
| Submission type       | Traditional                                         |
| Device classification | System, Test, Blood Glucose, Over The Counter (NBW) |
| Date received         | Sep 28, 2010                                        |
| Decision date         | Sep 15, 2011                                        |
| Days to decision      | 352 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/k102816/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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