

**K002621 GLUCOSURE BLOOD GLUCOSE MONITORING SYSTEM**Jan 22, 2001  
152 days to decisionK002621 · Product code: **CGA** · Chemistry  
Source: <https://www.510kdatabase.net/k002621/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Glucose Oxidase, Glucose (CGA)     |
| Date received         | Aug 23, 2000                       |
| Decision date         | Jan 22, 2001                       |
| Days to decision      | 152 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---|
| Company        | <b>Apex BioTechnology Corp.</b>         |
| Location       | Plymouth, MN, US                        |
| Contact        | STEVEN CREES                            |
| 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/k002621/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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