

**K944932 PHENOBARBITAL FLEX REAGENT CARTRIDGE**Dec 28, 1994  
83 days to decisionK944932 · Product code: **DLZ** · Toxicology  
Source: <https://www.510kdatabase.net/k944932/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Enzyme Immunoassay, Phenobarbital (DLZ) |
| Date received         | Oct 6, 1994                             |
| Decision date         | Dec 28, 1994                            |
| Days to decision      | 83 days                                 |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Dupont Medical Products</b>          |
| Location       | Wilmington, DE, US                      |
| Contact        | CAROLYN K GEORGE                        |
| 510(k) history | 28 submissions · 28 cleared · 1991-1995 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k944932/> 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 20, 2026