

**K882663 BARBITURATE ENZYME IMMUNOASSAY KIT**Sep 19, 1988  
84 days to decisionK882663 · Product code: **DIS** · Toxicology  
Source: <https://www.510kdatabase.net/k882663/>**SUBMISSION DETAILS**

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|                       |                                       |
|-----------------------|---------------------------------------|
| Decision              | Substantially Equivalent (Cleared)    |
| Submission type       | Traditional                           |
| Device classification | Enzyme Immunoassay, Barbiturate (DIS) |
| Date received         | Jun 27, 1988                          |
| Decision date         | Sep 19, 1988                          |
| Days to decision      | 84 days                               |
| Third-party review    | No                                    |

**APPLICANT**

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|----------------|---|
| Company        | <b>General Diagnostics</b>              |
| Location       | Mchenry, IL, US                         |
| Contact        | SUSAN M DURHAM                          |
| 510(k) history | 39 submissions · 39 cleared · 1976-1988 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k882663/>; 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 29, 2026