

K870953 PHENYTOIN FPIA REAGENT SETMar 31, 1987
21 days to decisionK870953 · Product code: **DIP** · Toxicology
Source: <https://www.510kdatabase.net/k870953/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Diphenylhydantoin (DIP) |
| Date received | Mar 10, 1987 |
| Decision date | Mar 31, 1987 |
| Days to decision | 21 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Sigma Diagnostics, Inc. |
| Location | Mchenry, IL, US |
| Contact | DENNIS MURRAY |
| 510(k) history | 164 submissions · 164 cleared · 1984-2002 |

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