

K802654 AMES TDA PRIMIDONE TESTNov 12, 1980
19 days to decisionK802654 · Product code: **DJD** · Toxicology
Source: <https://www.510kdatabase.net/k802654/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Primidone (DJD) |
| Date received | Oct 24, 1980 |
| Decision date | Nov 12, 1980 |
| Days to decision | 19 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Miles Laboratories, Inc. |
| Location | Mchenry, IL, US |
| 510(k) history | 158 submissions · 158 cleared · 1976-1988 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k802654/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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