

K012483 AMEDITECH IMMUTEST DRUG SCREEN OPIATESNov 30, 2001
120 days to decisionK012483 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k012483/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Opiates (DJG) |
| Date received | Aug 2, 2001 |
| Decision date | Nov 30, 2001 |
| Days to decision | 120 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Ameditech, Inc. |
| Location | San Diego, CA, US |
| Contact | JOHN WU |
| 510(k) history | 14 submissions · 14 cleared · 2001-2011 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012483/> Data sourced from FDA 510(k) public records (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. - Generated June 16, 2026