

K013482 ABUSCREEN ONLINE OPIATES 300 / 2000Dec 21, 2001
63 days to decisionK013482 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k013482/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Opiates (DJG) |
| Date received | Oct 19, 2001 |
| Decision date | Dec 21, 2001 |
| Days to decision | 63 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Roche Diagnostics Corp. |
| Location | Indianapolis, IN, US |
| Contact | KERWIN KAUFMAN |
| 510(k) history | 264 submissions · 263 cleared · 1999-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013482/> 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 9, 2026