

K990820 RAPIDONE - OPIATES TESTJul 15, 1999
126 days to decisionK990820 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k990820/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Opiates (DJG) |
| Date received | Mar 11, 1999 |
| Decision date | Jul 15, 1999 |
| Days to decision | 126 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | American Bio Medica Corp. |
| Location | Washington, DC, US |
| Contact | JOHN B DUBECK |
| 510(k) history | 30 submissions · 30 cleared · 1997-2017 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k990820/> 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