

K032279 ONLINE TDM AMIKAOct 10, 2003
78 days to decisionK032279 · Product code: **KLP** · Toxicology
Source: <https://www.510kdatabase.net/k032279/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Amikacin Serum Assay (KLP) |
| Date received | Jul 24, 2003 |
| Decision date | Oct 10, 2003 |
| Days to decision | 78 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/k032279/> 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