

K012312 IMMULITE 2000 TOBRAMYCN, MODELS L2KTC2 (2002 TESTS), L2KTC6 (600 TESTS)Aug 20, 2001
28 days to decisionK012312 · Product code: **KLB** · Toxicology
Source: <https://www.510kdatabase.net/k012312/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Radioimmunoassay, Tobramycin (KLB) |
| Date received | Jul 23, 2001 |
| Decision date | Aug 20, 2001 |
| Days to decision | 28 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Diagnostic Products Corp. |
| Location | Mchenry, IL, US |
| Contact | EDWARD M LEVINE |
| 510(k) history | 321 submissions · 321 cleared · 1976-2006 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012312/> 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 20, 2026