

K821669 AMES TDA GENTAMICIN TESTDec 15, 1982
191 days to decisionK821669 · Product code: **DJB** · Chemistry
Source: <https://www.510kdatabase.net/k821669/>**SUBMISSION DETAILS**

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| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Radioimmunoassay, Gentamicin (125-i), Second Antibody Sep. (DJB) |
| Date received | Jun 7, 1982 |
| Decision date | Dec 15, 1982 |
| Days to decision | 191 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Miles Laboratories, Inc. |
| Location | Mchenry, IL, US |
| 510(k) history | 158 submissions · 158 cleared · 1976-1988 |

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