

K790584 AMES TDA/GENTGMICINJun 15, 1979
80 days to decisionK790584 · Product code: **DJB** · Toxicology
Source: <https://www.510kdatabase.net/k790584/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Gentamicin (125-i), Second Antibody Sep. (DJB)
Date received	Mar 27, 1979
Decision date	Jun 15, 1979
Days to decision	80 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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