

K780323 QUANTITOPE 125-I GENTAMICIN RIA KITMar 17, 1978
18 days to decisionK780323 · Product code: **DJB** · Immunology
Source: <https://www.510kdatabase.net/k780323/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Gentamicin (125-i), Second Antibody Sep. (DJB)
Date received	Feb 27, 1978
Decision date	Mar 17, 1978
Days to decision	18 days
Third-party review	No

APPLICANT

Company	Kallestad Laboratories, Inc.
Location	Mchenry, IL, US
510(k) history	92 submissions · 92 cleared · 1976-1986

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