

**K800537 GAMMA STICK GENTAMICIN RIA KIT**Apr 24, 1980  
45 days to decisionK800537 · Product code: **DJB** · Toxicology  
Source: <https://www.510kdatabase.net/k800537/>**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	Mar 10, 1980
Decision date	Apr 24, 1980
Days to decision	45 days
Third-party review	No

**APPLICANT**

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Company	<b>Alpha Gamma Laboratory</b>
Location	Mchenry, IL, US
510(k) history	4 submissions · 4 cleared · 1978-1981

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k800537/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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