

K831297 PROTOTRO/PROTEOLYTIC ENZYME CONTROLJun 8, 1983
48 days to decisionK831297 · Product code: **JBQ** · Chemistry
Source: <https://www.510kdatabase.net/k831297/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antithrombin Iii Quantitation (JBQ)
Date received	Apr 21, 1983
Decision date	Jun 8, 1983
Days to decision	48 days
Third-party review	No

APPLICANT

Company	American Dade
Location	Mchenry, IL, US
510(k) history	149 submissions · 149 cleared · 1980-1987

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Device record: <https://www.510kdatabase.net/k831297/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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