

K800821 AFT TM SYSTEM ANTIMITOCHONDRIAL ANTIBODYApr 24, 1980
13 days to decisionK800821 · Product code: **DBM** · Immunology
Source: <https://www.510kdatabase.net/k800821/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antimitochondrial Antibody, Indirect Immunofluorescent, Antigen, Control (DBM)
Date received	Apr 11, 1980
Decision date	Apr 24, 1980
Days to decision	13 days
Third-party review	No

APPLICANT

Company	Calbiochem-Behring Corp.
Location	Mchenry, IL, US
510(k) history	41 submissions · 41 cleared · 1978-1983

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