

K812632 ACA IMMUNOGLOBIN M TEST PACKSep 29, 1981
14 days to decisionK812632 · Product code: **DFT** · Immunology
Source: <https://www.510kdatabase.net/k812632/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Igm, Antigen, Antiserum, Control (DFT)
Date received	Sep 15, 1981
Decision date	Sep 29, 1981
Days to decision	14 days
Third-party review	No

APPLICANT

Company	E.I. Dupont DE Nemours & Co., Inc.
Location	Mchenry, IL, US
510(k) history	253 submissions · 252 cleared · 1976-1996

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Device record: <https://www.510kdatabase.net/k812632/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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