FDA 510(k) Premarket Notification

K812625 ACA PLASMINOGEN TEST PACK

CLEARED

Sep 29, 1981
14 days to decision

K812625 · Product code: **DDX** · Immunology
Source: https://www.510kdatabase.net/k812625/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasminogen, Antigen, Antiserum, Control (DDX)
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