FDA 510(k) Premarket Notification

K831933 THEOPHYLLINE ACA CALIBRATOR

CLEARED

Jul 19, 1983
34 days to decision

K831933 · Product code: **DLJ** · Toxicology
Source: https://www.510kdatabase.net/k831933/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrators, Drug Specific (DLJ)
Date received	Jun 15, 1983
Decision date	Jul 19, 1983
Days to decision	34 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