FDA 510(k) Premarket Notification

K831209 GENTAMICIN CALIBRATOR -ACA

CLEARED

May 16, 1983
32 days to decision

K831209 · Product code: **DLJ** · Toxicology
Source: https://www.510kdatabase.net/k831209/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrators, Drug Specific (DLJ)
Date received	Apr 14, 1983
Decision date	May 16, 1983
Days to decision	32 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