FDA 510(k) Premarket Notification

K812677 UNITEST-POTASSIUM

CLEARED

Oct 2, 1981
10 days to decision

K812677 · Product code: **CEJ** · Chemistry
Source: https://www.510kdatabase.net/k812677/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tetraphenyl Borate, Colorimetry, Potassium (CEJ)
Date received	Sep 22, 1981
Decision date	Oct 2, 1981
Days to decision	10 days
Third-party review	No

APPLICANT

Company	**Biodynamics Corp.**
Location	Walker, MI, US
510(k) history	21 submissions · 21 cleared · 1980-2006

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k812677/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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