FDA 510(k) Premarket Notification

K821995 SOLUTION ADMINISTRATION SET (W/O NEEDLE)

CLEARED

Aug 5, 1982
29 days to decision

K821995 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k821995/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Jul 7, 1982
Decision date	Aug 5, 1982
Days to decision	29 days
Third-party review	No

APPLICANT

Company	**Bertex Laboratories, Inc.**
Location	Mchenry, IL, US
510(k) history	1 submissions · 1 cleared · 1982-1982

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k821995/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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