FDA 510(k) Premarket Notification

K872795 CHANGE IN STERILITY TEST METHOD & TEST LAB. SITE

CLEARED

Sep 4, 1987
58 days to decision

K872795 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k872795/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Jul 8, 1987
Decision date	Sep 4, 1987
Days to decision	58 days
Third-party review	No

APPLICANT

Company	**Medex, Inc.**
Location	Mchenry, IL, US
Contact	CLINT LAWSON
510(k) history	48 submissions · 46 cleared · 1977-2005