FDA 510(k) Premarket Notification

K963659 EXEL I.V. ADMINISTRATION SET

CLEARED

Dec 16, 1997
469 days to decision

K963659 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k963659/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Sep 3, 1996
Decision date	Dec 16, 1997
Days to decision	469 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Exel Intl.**
Location	Culver City, CA, US
Contact	ARMAND HAMID
510(k) history	18 submissions · 18 cleared · 1986-2000