FDA 510(k) Premarket Notification

K912860 INTRAVASCULAR ADMINISTRATION SETS

CLEARED

Aug 28, 1991
62 days to decision

K912860 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k912860/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Jun 27, 1991
Decision date	Aug 28, 1991
Days to decision	62 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Pacific Device, Inc.**
Location	San Diego, CA, US
Contact	JIM CAPUTO
510(k) history	5 submissions · 5 cleared · 1990-1997