FDA 510(k) Premarket Notification

K071421 PROMEPLA INTRAVASCULAR ADMINISTRATION SET AND EXTENSION SET

CLEARED

Oct 4, 2007
135 days to decision

K071421 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k071421/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	May 22, 2007
Decision date	Oct 4, 2007
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Promepla**
Location	Chevy Chase, MD, US
Contact	PATSY J TRISLER
510(k) history	1 submissions · 1 cleared · 2007-2007