FDA 510(k) Premarket Notification

K020424 V SET

CLEARED

Aug 29, 2003
567 days to decision

K020424 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k020424/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Feb 8, 2002
Decision date	Aug 29, 2003
Days to decision	567 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Hennig Enterprises Europe Srl**
Location	Perth, AU
Contact	GEORGE O'NEIL
510(k) history	2 submissions · 2 cleared · 2003-2003