FDA 510(k) Premarket Notification

K972663 SMART SET

CLEARED

Sep 2, 1997
56 days to decision

K972663 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k972663/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Jul 8, 1997
Decision date	Sep 2, 1997
Days to decision	56 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Top Spins, Inc.**
Location	Ann Arbor, MI, US
Contact	MARTIN R PRINCE
510(k) history	3 submissions · 3 cleared · 1997-2016