FDA 510(k) Premarket Notification

K894446 ANGEION HEMOSTASIS VALVE INTRODUCER

CLEARED

Nov 30, 1989
136 days to decision

K894446 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k894446/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jul 17, 1989
Decision date	Nov 30, 1989
Days to decision	136 days
Third-party review	No

APPLICANT

Company	**Angeion Corp.**
Location	Plymouth, MN, US
Contact	GREGORY G BRUCKER
510(k) history	7 submissions · 7 cleared · 1987-1993