FDA 510(k) Premarket Notification

K942977 NOVOSTE PULSE PLUS BLOOD CONTAINMENT DEVICE

CLEARED

Dec 28, 1995
556 days to decision

K942977 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k942977/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jun 20, 1994
Decision date	Dec 28, 1995
Days to decision	556 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Novoste Corp.**
Location	Miami, FL, US
Contact	JOAN M MACDONALD
510(k) history	5 submissions · 5 cleared · 1988-1995