FDA 510(k) Premarket Notification

K873597 TUBING, POLYETHYLENE

CLEARED

Nov 12, 1987
69 days to decision

K873597 · Product code: **DXT** · Cardiovascular
Source: https://www.510kdatabase.net/k873597/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Sep 4, 1987
Decision date	Nov 12, 1987
Days to decision	69 days
Third-party review	No

APPLICANT

Company	**Coeur Laboratories, Inc.**
Location	NC, US
Contact	PRISCILLA DENSMORE
510(k) history	10 submissions · 10 cleared · 1983-1997