FDA 510(k) Premarket Notification

K902475 CARDIO-PAK ANGIOGRAPHY CUSTOM PACKS

CLEARED

Dec 3, 1990
182 days to decision

K902475 · Product code: **DXT** · Cardiovascular
Source: https://www.510kdatabase.net/k902475/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Jun 4, 1990
Decision date	Dec 3, 1990
Days to decision	182 days
Third-party review	No

APPLICANT

Company	**Cardio-Pak**
Location	Billings, MT, US
Contact	JEROME E DERNBACH
510(k) history	1 submissions · 1 cleared · 1990-1990