FDA 510(k) Premarket Notification

K902221 MODIFIED ANGIOGRAPHIC INJECTOR AND SYRINGE

CLEARED

Aug 8, 1990
83 days to decision

K902221 · Product code: **DXT** · Cardiovascular
Source: https://www.510kdatabase.net/k902221/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	May 17, 1990
Decision date	Aug 8, 1990
Days to decision	83 days
Third-party review	No

APPLICANT

Company	**Mallinckrodt Group, Inc.**
Location	Mchenry, IL, US
Contact	THOMAS F DONOHUE
Website	https://www.mallinckrodt.com
510(k) history	27 submissions · 27 cleared · 1976-1995

Mallinckrodt Group, Inc. is a pharmaceutical and medical device company based in McHenry, US. Now part of a restructured corporate family following a 2025 merger and subsequent spin-off, the company's regulatory history reflects its historical role in medical device manufacturing. Mallinckrodt received FDA 510(k) clearances from total submissions, with no denied submissions on record. The company's cleared devices span radiology, cardiovascular, gastroenterology, and surgical specialties, with clearances issued between 1976 and 1995. This regulatory record is now historic...