

K912944 CT 8000 DIGITAL INJECTION SYSTEMFeb 4, 1992
214 days to decisionK912944 · Product code: **DXT** · Cardiovascular
Source: <https://www.510kdatabase.net/k912944/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Jul 5, 1991
Decision date	Feb 4, 1992
Days to decision	214 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Mallinckrodt Group, Inc.
Location	Mchenry, IL, US
Contact	MARK L FREIDMAN
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...
