

K945053 LF CT HIG PRESSURE CATHETERSMay 19, 1995
217 days to decisionK945053 · Product code: **FOZ** · General Hospital
Source: <https://www.510kdatabase.net/k945053/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Oct 14, 1994
Decision date	May 19, 1995
Days to decision	217 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Mallinckrodt Group, Inc.
Location	Mchenry, IL, US
Contact	M L FRIEDMAN
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...
