

K945140 URO-FLOMar 8, 1995
139 days to decisionK945140 · Product code: **LJH** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k945140/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Irrigation, Urological (LJH)
Date received	Oct 20, 1994
Decision date	Mar 8, 1995
Days to decision	139 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...
