

**K943122 SURGICAL DRAPES**Sep 7, 1994  
70 days to decisionK943122 · Product code: **KKX** · General Hospital  
Source: <https://www.510kdatabase.net/k943122/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drape, Surgical (KKX)
Date received	Jun 29, 1994
Decision date	Sep 7, 1994
Days to decision	70 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Mallinckrodt Group, Inc.</b>
Location	Mchenry, IL, US
Contact	M.L. FRIEDMAN, PH.D.
Website	<a href="https://www.mallinckrodt.com">https://www.mallinckrodt.com</a>
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...

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