

**K770836 ULTIMAT L4 X L4, LIEBEL-FLARSHEIM**May 26, 1977  
20 days to decisionK770836 · Product code: **KPX** · Pathology  
Source: <https://www.510kdatabase.net/k770836/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Changer, Radiographic Film/cassette (KPX)
Date received	May 6, 1977
Decision date	May 26, 1977
Days to decision	20 days
Third-party review	No

**APPLICANT**

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Company	<b>Mallinckrodt Group, Inc.</b>
Location	Mchenry, IL, US
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...