

**K901323 HYDRA VIEW IMAGING SYSTEM**Apr 25, 1990  
35 days to decisionK901323 · Product code: **JAA** · Radiology  
Source: <https://www.510kdatabase.net/k901323/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Mar 21, 1990
Decision date	Apr 25, 1990
Days to decision	35 days
Third-party review	No

**APPLICANT**

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Company	<b>Mallinckrodt Group, Inc.</b>
Location	McHenry, IL, US
Contact	F DONOHUE
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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Device record: <https://www.510kdatabase.net/k901323/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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