

**K904145 HYDRA VISION UROLOGICAL X-RAY SYSTEM**Dec 13, 1990  
97 days to decisionK904145 · Product code: **KPR** · Radiology  
Source: <https://www.510kdatabase.net/k904145/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Sep 7, 1990
Decision date	Dec 13, 1990
Days to decision	97 days
Third-party review	No

**APPLICANT**

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Company	<b>Mallinckrodt Group, Inc.</b>
Location	McHenry, IL, US
Contact	THOMAS 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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