

**K934664 HYDRAGOWN**May 24, 1994  
238 days to decisionK934664 · Product code: **FYA** · General Hospital  
Source: <https://www.510kdatabase.net/k934664/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Sep 28, 1993
Decision date	May 24, 1994
Days to decision	238 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
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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