

K781578 RIA QUANT B-HCG TEST KITOct 10, 1978
25 days to decisionK781578 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k781578/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Sep 15, 1978
Decision date	Oct 10, 1978
Days to decision	25 days
Third-party review	No

APPLICANT

Company	Mallinckrodt Critical Care
Location	Mchenry, IL, US
Website	https://www.mallinckrodt.com
510(k) history	92 submissions · 92 cleared · 1976-1989

Mallinckrodt Critical Care is a medical device manufacturer based in McHenry, US. Now part of Mallinckrodt plc following a 2025 merger and subsequent restructuring, the company maintains a significant historical regulatory record in critical care and specialty medical devices. The company received FDA 510(k) clearances from total submissions between 1976 and 1989. Device clearances span anesthesiology, cardiovascular, gastroenterology, and general hospital categories. Notable cleared products include tracheal tubes, temperature monitoring systems, catheters, and related c...

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