

**K801125 SPAC T3 RIA TEST KIT**Jun 9, 1980  
28 days to decisionK801125 · Product code: **CDP** · Chemistry  
Source: <https://www.510kdatabase.net/k801125/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Total Triiodothyronine (CDP)
Date received	May 12, 1980
Decision date	Jun 9, 1980
Days to decision	28 days
Third-party review	No

**APPLICANT**

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Company	<b>Mallinckrodt Critical Care</b>
Location	Mchenry, IL, US
Website	<a href="https://www.mallinckrodt.com">https://www.mallinckrodt.com</a>
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...