

K821151 RIA-QUANT FPA TEST KITJul 22, 1982
87 days to decisionK821151 · Product code: **DAN** · Immunology
Source: <https://www.510kdatabase.net/k821151/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinopeptide A, Antigen, Antiserum, Control (DAN)
Date received	Apr 26, 1982
Decision date	Jul 22, 1982
Days to decision	87 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...