

**K820001 CORONARY INFUSION KIT**Jan 29, 1982  
25 days to decisionK820001 · Product code: **DQO** · CardiovascularSource: <https://www.510kdatabase.net/k820001/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Jan 4, 1982
Decision date	Jan 29, 1982
Days to decision	25 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...

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