

**K874605 HI-LO TEMP(R) MYOCARDIAL TEMPERATURE SENSOR**Feb 2, 1988  
85 days to decisionK874605 · Product code: **KRI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k874605/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessory Equipment, Cardiopulmonary Bypass (KRI)
Date received	Nov 9, 1987
Decision date	Feb 2, 1988
Days to decision	85 days
Third-party review	No

**APPLICANT**

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Company	<b>Mallinckrodt Critical Care</b>
Location	Mchenry, IL, US
Contact	PHILIP E WIEGERT
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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