

K843410 FLOW-DIRECTED PEDIATRIC THERMODIL- CATHNov 20, 1984
81 days to decisionK843410 · Product code: **KRB** · CardiovascularSource: <https://www.510kdatabase.net/k843410/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Probe, Thermodilution (KRB)
Date received	Aug 31, 1984
Decision date	Nov 20, 1984
Days to decision	81 days
Third-party review	No

APPLICANT

Company	Andover Medical, Inc.
Location	Mchenry, IL, US
Contact	ROBERT TETU
Website	https://www.andovermedical.com
510(k) history	21 submissions · 21 cleared · 1976-1991

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k843410/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026