

K771663 PROBE & CATHETERSep 20, 1977
21 days to decisionK771663 · Product code: **KRB** · CardiovascularSource: <https://www.510kdatabase.net/k771663/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Probe, Thermodilution (KRB)
Date received	Aug 30, 1977
Decision date	Sep 20, 1977
Days to decision	21 days
Third-party review	No

APPLICANT

Company	Edwards Laboratories
Location	Mchenry, IL, US
510(k) history	12 submissions · 11 cleared · 1976-1980

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k771663/> 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 July 9, 2026