

K821099 HEPARIN COATED THERMODILUTION CATHETERMay 18, 1982
28 days to decisionK821099 · Product code: **DYG** · CardiovascularSource: <https://www.510kdatabase.net/k821099/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Flow Directed (DYG)
Date received	Apr 20, 1982
Decision date	May 18, 1982
Days to decision	28 days
Third-party review	No

APPLICANT

Company	Kma, Inc.
Location	Walker, MI, US
510(k) history	3 submissions · 3 cleared · 1980-1985

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k821099/> 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