

K822034 BALLOON WEDGE PRESSURE CATHETERAug 24, 1982
43 days to decisionK822034 · Product code: **DYG** · CardiovascularSource: <https://www.510kdatabase.net/k822034/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Flow Directed (DYG)
Date received	Jul 12, 1982
Decision date	Aug 24, 1982
Days to decision	43 days
Third-party review	No

APPLICANT

Company	Ziehm International, Inc.
Location	Annapolis, MD, US
510(k) history	16 submissions · 16 cleared · 1982-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k822034/>; 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 19, 2026