

K925049 QUEST HEART INSULATION PADFeb 1, 1994
483 days to decisionK925049 · Product code: **DWF** · Cardiovascular
Source: <https://www.510kdatabase.net/k925049/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Oct 6, 1992
Decision date	Feb 1, 1994
Days to decision	483 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Quest Medical, Inc.
Location	Walker, MI, US
Contact	DREW JOHNSON
510(k) history	39 submissions · 39 cleared · 1980-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k925049/> 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 June 28, 2026