FDA 510(k) Premarket Notification

K925049 QUEST HEART INSULATION PAD

CLEARED

Feb 1, 1994
483 days to decision

K925049 · 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