

**K941921 BIO-MEDICUS BIO-CONSOLE MODELS 540,
540A,B,C,D,E, & 550**Jul 20, 1994
91 days to decisionK941921 · Product code: **DWA** · Cardiovascular
Source: <https://www.510kdatabase.net/k941921/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control, Pump Speed, Cardiopulmonary Bypass (DWA)
Date received	Apr 20, 1994
Decision date	Jul 20, 1994
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Bio-Medicus, Inc.
Location	Eden Prairie, MN, US
Contact	THOMAS JOHNSEN
510(k) history	13 submissions · 13 cleared · 1992-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k941921/> 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 14, 2026