

K910568 MODEL 5866-46 SLEEVE KITApr 9, 1991
57 days to decisionK910568 · Product code: **DTP** · Cardiovascular
Source: <https://www.510kdatabase.net/k910568/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Defoamer, Cardiopulmonary Bypass (DTP)
Date received	Feb 11, 1991
Decision date	Apr 9, 1991
Days to decision	57 days
Third-party review	No

APPLICANT

Company	Medtronic Vascular
Location	Walker, MI, US
Contact	TRACY MALM
510(k) history	475 submissions · 453 cleared · 1977-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k910568/>; 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 18, 2026