

**K003724 CBMYOTHERM XP CARDIOPLEGIA DELIVERY
SYSTEM WITH CARMEDA BIOACTIVE SURFACE, MODELS
CB41 AND CB41-B**Dec 21, 2000
17 days to decisionK003724 · Product code: **DTR** · Cardiovascular
Source: <https://www.510kdatabase.net/k003724/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Dec 4, 2000
Decision date	Dec 21, 2000
Days to decision	17 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003724/> 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