

**K973475 CARMEDA COATED CARDIOTHERM BLOOD
CARDIOPLEGIA SYSTEMS (CBCTXXX SERIES AND
CBCTXXXBR SERIES)**

Nov 20, 1997
69 days to decision

K973475 · Product code: **DTR** · Cardiovascular
Source: <https://www.510kdatabase.net/k973475/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Sep 12, 1997
Decision date	Nov 20, 1997
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k973475/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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