

**K000379 MODIFICATION TO AFFINITY 38 MICRO ARTERIAL  
BLOOD FILTER WITH CARMEDA BIOACTIVE SURFACE,  
MODELS CB351/CB352**Feb 16, 2000  
9 days to decisionK000379 · Product code: **DTM** · Cardiovascular  
Source: <https://www.510kdatabase.net/k000379/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Filter, Blood, Cardiopulmonary Bypass, Arterial Line (DTM)
Date received	Feb 7, 2000
Decision date	Feb 16, 2000
Days to decision	9 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k000379/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026