

**K001138 AFFINITY 20 MICRON ARTERIAL BLOOD FILTER WITH  
CARMEDA BIOACTIVE SURFACE, MODELS CB353/CB354**Apr 27, 2000  
17 days to decisionK001138 · Product code: **DTM** · Cardiovascular  
Source: <https://www.510kdatabase.net/k001138/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Filter, Blood, Cardiopulmonary Bypass, Arterial Line (DTM)
Date received	Apr 10, 2000
Decision date	Apr 27, 2000
Days to decision	17 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/k001138/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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