

**K071253 AFFINITY PEDIATRIC ARTERIAL FILTER, MODEL S4014 AND WITH CARMEDA BIOACTIVE SURFACE, MODEL CB4014**Jul 3, 2007  
60 days to decisionK071253 · Product code: **DTM** · Cardiovascular  
Source: <https://www.510kdatabase.net/k071253/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Blood, Cardiopulmonary Bypass, Arterial Line (DTM)
Date received	May 4, 2007
Decision date	Jul 3, 2007
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Vascular</b>
Location	Walker, MI, US
Contact	JESSICA SIXBERRY
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/k071253/> 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 13, 2026