

**K994208 AFFINITY 20 MICRON ARTERIAL BLOOD FILTER,  
MODEL 353/354**Jan 13, 2000  
30 days to decisionK994208 · Product code: **DTM** · Cardiovascular  
Source: <https://www.510kdatabase.net/k994208/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Filter, Blood, Cardiopulmonary Bypass, Arterial Line (DTM)
Date received	Dec 14, 1999
Decision date	Jan 13, 2000
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Perfusion Systems</b>
Location	Minneapolis, MN, US
Contact	MARIE HOLM
510(k) history	29 submissions · 29 cleared · 2000-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k994208/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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