

**K013084 AFFINITY 38 MICON ARTERIAL FILTER WITH TRILLIUM BIOPASSIVE SURFACE, MODEL 351T**

Sep 27, 2001  
13 days to decision

K013084 · Product code: **DTM** · Cardiovascular  
Source: <https://www.510kdatabase.net/k013084/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Filter, Blood, Cardiopulmonary Bypass, Arterial Line (DTM)
Date received	Sep 14, 2001
Decision date	Sep 27, 2001
Days to decision	13 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/k013084/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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