

K033468 AFFINITY 20U ARTERIAL FILTER WITH TRILLIUM BIOSURFACENov 14, 2003
11 days to decisionK033468 · Product code: **DTM** · Cardiovascular
Source: <https://www.510kdatabase.net/k033468/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Filter, Blood, Cardiopulmonary Bypass, Arterial Line (DTM)
Date received	Nov 3, 2003
Decision date	Nov 14, 2003
Days to decision	11 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Perfusion Systems
Location	Minneapolis, MN, US
Contact	MICHELE PYFFEROEN
510(k) history	29 submissions · 29 cleared · 2000-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k033468/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026