

K121209 TERUMO PALL AL20X ARTERIAL FILTERMay 8, 2012
18 days to decisionK121209 · Product code: **DTM** · CardiovascularSource: <https://www.510kdatabase.net/k121209/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Filter, Blood, Cardiopulmonary Bypass, Arterial Line (DTM)
Date received	Apr 20, 2012
Decision date	May 8, 2012
Days to decision	18 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Terumo Cardiovascular Systems Corporation
Location	Elkton, MD, US
Contact	SUZANNE GRENIER
510(k) history	29 submissions · 29 cleared · 2002-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121209/> 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 June 14, 2026