FDA 510(k) Premarket Notification

CLEARED

K251744 Affinity Pixie™ Arterial Filter with Balance™ Biosurface

Jan 16, 2026
224 days to decision

K251744 · Product code: **DTM** · Cardiovascular
Source: https://www.510kdatabase.net/k251744/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Filter, Blood, Cardiopulmonary Bypass, Arterial Line (DTM)
Date received	Jun 6, 2025
Decision date	Jan 16, 2026
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Affinity® Pediatric Arterial Blood Filter

APPLICANT

Company	**Medtronic**
Location	Minneapolis, MN, US
Contact	Makella Daley
Website	http://www.medtronic.com/us-en/index.html
510(k) history	32 submissions · 32 cleared · 2007-2026

Medtronic is an American-Irish medical device company with operational headquarters in Minneapolis, Minnesota. The company operates globally across more than 150 countries and is the largest medical device company in the world by revenue. Medtronic has received FDA 510(k) clearances from total submissions since 2007. The company's regulatory portfolio is dominated by cardiovascular devices, including oxygenation systems, arterial filters, cardioplegia delivery systems, and catheter-based interventions. Medtronic also maintains a significant presence in orthopedic spinal s...