

**K100646 AFFINITY PIXIE ARTERIAL FILTER WITH BALANCE  
BIOSURFACE**Dec 16, 2010  
286 days to decisionK100646 · Product code: **DTM** · Cardiovascular  
Source: <https://www.510kdatabase.net/k100646/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Blood, Cardiopulmonary Bypass, Arterial Line (DTM)
Date received	Mar 5, 2010
Decision date	Dec 16, 2010
Days to decision	286 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Medtronic, Inc.</b>
Location	Mounds View, MN, US
Contact	JEFFREY L KOLL
Website	<a href="https://www.medtronic.com">https://www.medtronic.com</a>
510(k) history	209 submissions · 208 cleared · 1981-2026

Medtronic, Inc. is a global medical device manufacturer headquartered in Mounds View, United States. The company develops and markets a broad range of medical devices across multiple therapeutic areas. Medtronic maintains a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions since 1981. The company specializes primarily in Cardiovascular devices, which represent 82% of its submission portfolio. Recent clearances include coronary perfusion cannulae, intracoronary shunts, venous cannulae, guidewires, deflectable catheter systems,...

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100646/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 20, 2026