

**K100645 AFFINITY PIXIE OXYGENATION SYSTEM WITH
CARMEDA BIOACTIVE SURFACE OR BALANCE BIOSURFACE**Sep 14, 2012
924 days to decisionK100645 · Product code: DTZ · Cardiovascular
Source: <https://www.510kdatabase.net/k100645/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Mar 5, 2010
Decision date	Sep 14, 2012
Days to decision	924 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic, Inc.
Location	Mounds View, MN, US
Contact	JESSICA SIXBERRY
Website	https://www.medtronic.com
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

Device record: <https://www.510kdatabase.net/k100645/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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