

# K142784 Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface, Affinity Fusion Oxygenator with Integrated Arterial Filter and Carmeda BioActive Surface

Oct 24, 2014  
28 days to decision

K142784 · Product code: **DTZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k142784/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Sep 26, 2014
Decision date	Oct 24, 2014
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>Medtronic, Inc.</b>
Location	Mounds View, MN, US
Contact	Lisa Stone
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,...