

**K122914 AFFINITY FUSION CARDIOTOMY/VENOUS  
RESERVIOR WITH BALANCE BIOSURFACE MODEL BB841,  
AFFINITY FUSION CARDIOTOMY/ VENOUS RESE**Jan 9, 2013  
110 days to decisionK122914 · Product code: DTN · Cardiovascular  
Source: <https://www.510kdatabase.net/k122914/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Sep 21, 2012
Decision date	Jan 9, 2013
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic, Inc.</b>
Location	Mounds View, MN, US
Contact	JULIA A NELSON
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,...