

**K131964 BIO-CONSOLE 560 EXTRACORPOREAL BLOOD PUMPING CONSOLE**Jul 24, 2013  
27 days to decisionK131964 · Product code: **DWA** · Cardiovascular  
Source: <https://www.510kdatabase.net/k131964/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Control, Pump Speed, Cardiopulmonary Bypass (DWA)
Date received	Jun 27, 2013
Decision date	Jul 24, 2013
Days to decision	27 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,...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k131964/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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