

**K162054 Medtronic Temporary External Pacemaker 53401**Oct 18, 2016  
85 days to decisionK162054 · Product code: **DTE** · Cardiovascular  
Source: <https://www.510kdatabase.net/k162054/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pulse-generator, Pacemaker, External (DTE)
Date received	Jul 25, 2016
Decision date	Oct 18, 2016
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic, Inc.</b>
Location	Mounds View, MN, US
Contact	SYED SUMRAN MOHIUDDIN
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/k162054/>; 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 2, 2026