

**K250075 Medtronic Stedi Extra Support Guidewire**Jun 13, 2025  
154 days to decisionK250075 · Product code: **DQX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k250075/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Wire, Guide, Catheter (DQX)        |
| Date received         | Jan 10, 2025                       |
| Decision date         | Jun 13, 2025                       |
| Days to decision      | 154 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Medtronic, Inc.</b>  |
| Location       | Mounds View, MN, US   |
| Contact        | Hillary Barasa  |
| 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/k250075/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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