

**K250135 WAVE Clinical Platform (2.0.000)**Jan 16, 2026  
364 days to decisionK250135 · Product code: **MWI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k250135/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional  |
| Device classification | Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI) |
| Date received         | Jan 17, 2025   |
| Decision date         | Jan 16, 2026   |
| Days to decision      | 364 days   |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|--|
| Company        | <b>Baxter Healthcare Corp/ Excel Medical</b> |
| Location       | Palm Beach Gardens, FL, US                   |
| Contact        | Gena Wolfe                                   |
| 510(k) history | 1 submissions · 1 cleared · 2026-2026        |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250135/> 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 May 14, 2026