

**K043549 INFINITY GATEWAY SUITE, VF4**Jan 21, 2005  
29 days to decisionK043549 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k043549/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Special  |
| Device classification | Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX) |
| Date received         | Dec 23, 2004   |
| Decision date         | Jan 21, 2005   |
| Days to decision      | 29 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Draeger Medical Systems, Inc.</b>    |
| Location       | Danvers, MA, US                         |
| Contact        | PENELOPE H GRECO                        |
| 510(k) history | 48 submissions · 48 cleared · 2003-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043549/> 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 24, 2026