

K233834 Infinity Gateway SuiteJul 12, 2024
221 days to decisionK233834 · Product code: **MSX** · Cardiovascular
Source: <https://www.510kdatabase.net/k233834/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Network And Communication, Physiological Monitors (MSX) |
| Date received | Dec 4, 2023 |
| Decision date | Jul 12, 2024 |
| Days to decision | 221 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Draeger Medical Systems, Inc. |
| Location | Danvers, MA, US |
| Contact | Chris Riel |
| 510(k) history | 48 submissions · 48 cleared · 2003-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233834/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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