

**K972242 REVEAL INSERTABLE LOOP RECORDER (ILR)
SYSTEM**Jan 16, 1998
214 days to decisionK972242 · Product code: **MXC** · Cardiovascular
Source: <https://www.510kdatabase.net/k972242/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent - ST |
| Submission type | Traditional |
| Device classification | Recorder, Event, Implantable Cardiac, (without Arrhythmia Detection) (MXC) |
| Date received | Jun 16, 1997 |
| Decision date | Jan 16, 1998 |
| Days to decision | 214 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Medtronic Vascular |
| Location | Walker, MI, US |
| Contact | NORA K HADDING |
| 510(k) history | 475 submissions · 453 cleared · 1977-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k972242/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026