

K130707 ISIRONA MAGELLANNov 20, 2013
250 days to decisionK130707 · Product code: **MSX** · Cardiovascular
Source: <https://www.510kdatabase.net/k130707/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Network And Communication, Physiological Monitors (MSX) |
| Date received | Mar 15, 2013 |
| Decision date | Nov 20, 2013 |
| Days to decision | 250 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Isirona, LLC |
| Location | Nederland, CO, US |
| Contact | THOMAS KROENKE |
| 510(k) history | 1 submissions · 1 cleared · 2013-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k130707/> 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 June 8, 2026