

**K982617 TRACER**Apr 9, 1999  
256 days to decisionK982617 · Product code: **MWJ** · CardiovascularSource: <https://www.510kdatabase.net/k982617/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph, Ambulatory (without Analysis) (MWJ)
Date received	Jul 27, 1998
Decision date	Apr 9, 1999
Days to decision	256 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Heartland Medical Systems, Inc.</b>
Location	Newbury Park, CA, US
Contact	JOHN A HUMPHREY
510(k) history	1 submissions · 1 cleared · 1999-1999

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k982617/> 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 July 4, 2026