

**K982843 CMS-2000**Nov 10, 1998  
90 days to decisionK982843 · Product code: **MWJ** · CardiovascularSource: <https://www.510kdatabase.net/k982843/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph, Ambulatory (without Analysis) (MWJ)
Date received	Aug 12, 1998
Decision date	Nov 10, 1998
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Industrial Technology Research Institute</b>
Location	Hsinchu,, TW
Contact	MING-CHENG CHANG
510(k) history	1 submissions · 1 cleared · 1998-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k982843/> 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