

**K011000 TRAM 2001 MODULE**Jun 29, 2001  
87 days to decisionK011000 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k011000/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Apr 3, 2001
Decision date	Jun 29, 2001
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>General Electric Medical Systems Information Techn</b>
Location	Sugarland, TX, US
Contact	KAREN WEBB
510(k) history	33 submissions · 33 cleared · 1999-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011000/> 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 May 19, 2026