

**K911646 NGM ESTP MODULE**Feb 21, 1992  
312 days to decisionK911646 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k911646/>**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 15, 1991
Decision date	Feb 21, 1992
Days to decision	312 days
Third-party review	No

**APPLICANT**

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Company	<b>Datex Division Instrumentarium Corp.</b>
Location	Walker, MI, US
Contact	VINCENT RAUSCHER
510(k) history	55 submissions · 55 cleared · 1982-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k911646/>; 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 26, 2026