

**K001348 ST/AR ST AND ARRHYTHMIA SOFTWARE**May 17, 2000  
19 days to decisionK001348 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k001348/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Apr 28, 2000
Decision date	May 17, 2000
Days to decision	19 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Agilent Technologies, Inc.</b>
Location	Pittsburgh, PA, US
Contact	DAVE OSBORN
Website	<a href="http://www.agilent.com">http://www.agilent.com</a>
510(k) history	30 submissions · 30 cleared · 1985-2017

Agilent Technologies, Inc. is an American global company that provides instruments, software, services, and consumables for laboratories. Headquartered in Santa Clara, California, Agilent was established in 1999 as a spin-off from Hewlett-Packard. The company has received FDA 510(k) clearances from total submissions. Cardiovascular devices represent the dominant focus, accounting for approximately 80% of regulatory submissions. Agilent's FDA 510(k) clearance history spans from 1985 to 2017, establishing a long track record in medical device regulation. Notable cleared dev...

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