

**K003621 ST/AR ST AND ARRHYTHMIA SOFTWARE, MODEL
RELEASE D.0**Dec 20, 2000
26 days to decisionK003621 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k003621/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Nov 24, 2000
Decision date	Dec 20, 2000
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Agilent Technologies, Inc.
Location	Pittsburgh, PA, US
Contact	DAVE OSBORN
Website	http://www.agilent.com
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...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003621/> Data sourced from FDA 510(k) public records (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. - Generated May 19, 2026