

**K014261 ST/AR ST AND ARRHYTHMIA SOFTWARE, MODEL
RELEASE E.0**Feb 12, 2002
47 days to decisionK014261 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k014261/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Dec 27, 2001
Decision date	Feb 12, 2002
Days to decision	47 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Philips Medical Systems, Inc.
Location	Mchenry, IL, US
Contact	DAVE OSBORN
510(k) history	111 submissions · 110 cleared · 1983-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k014261/> 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 17, 2026