

**K021251 ST/AR ST AND ARRHYTHMIA SOFTWARE, RELEASE
E.I.**May 7, 2002
18 days to decisionK021251 · Product code: **DSI** · Cardiovascular
Source: <https://www.510kdatabase.net/k021251/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Apr 19, 2002
Decision date	May 7, 2002
Days to decision	18 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Philips Medical Systems
Location	Seattle, WA, US
Contact	DAVE OSBORN
510(k) history	107 submissions · 105 cleared · 2002-2021

Philips Medical Systems is a Dutch multinational health technology company headquartered in Amsterdam with U.S. operations based in Seattle. The company evolved from a consumer electronics conglomerate founded in 1891 to a healthcare-focused organization. Philips Medical Systems has received FDA 510(k) clearances from total submissions between 2002 and 2021. The company's regulatory focus centered on Cardiovascular devices, which represented 79% of all submissions. This historical record reflects the company's significant presence in diagnostic ultrasound systems and pati...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k021251/> 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 June 28, 2026