

K844392 CARDIOSTAT 1 ECG RECORDERApr 11, 1985
149 days to decisionK844392 · Product code: **DPS** · CardiovascularSource: <https://www.510kdatabase.net/k844392/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Nov 13, 1984
Decision date	Apr 11, 1985
Days to decision	149 days
Third-party review	No

APPLICANT

Company	Siemens Elema AB
Location	Mchenry, IL, US
Contact	JOSEPH R RADZIUS
510(k) history	63 submissions · 60 cleared · 1978-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k844392/>; 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 22, 2026