

**K950989 CARDIOSMART**May 13, 1996  
437 days to decisionK950989 · Product code: **DPS** · Cardiovascular  
Source: <https://www.510kdatabase.net/k950989/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Mar 3, 1995
Decision date	May 13, 1996
Days to decision	437 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hellige GmbH</b>
Location	D7800 Freiburg Im Breisga, DE
Contact	KLAUS RUDOLF
510(k) history	2 submissions · 2 cleared · 1995-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k950989/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 5, 2026