

**K950944 AMBULATORY (HOLTER) RECORDING SYSTEM**Jun 18, 1996  
487 days to decisionK950944 · Product code: **DQK** · Cardiovascular  
Source: <https://www.510kdatabase.net/k950944/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Feb 17, 1995
Decision date	Jun 18, 1996
Days to decision	487 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Biosensor Corp.</b>
Location	Walker, MI, US
Contact	DARREN D DERSHEM
510(k) history	10 submissions · 10 cleared · 1983-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k950944/> 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 May 20, 2026