

**K860950 SCM-400 HOLTER SYSTEM**May 2, 1986  
51 days to decisionK860950 · Product code: **DSI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k860950/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Mar 12, 1986
Decision date	May 2, 1986
Days to decision	51 days
Third-party review	No

**APPLICANT**

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Company	<b>Fukuda Denshi USA, Inc.</b>
Location	Mchenry, IL, US
Contact	DON ANDRESEN
510(k) history	68 submissions · 68 cleared · 1984-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k860950/>, 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 18, 2026