

**K903704 FUKUDA DENSHI MODEL FCP-2201 MODIFICATION**Sep 7, 1990  
87 days to decisionK903704 · Product code: **DSI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k903704/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Jun 12, 1990
Decision date	Sep 7, 1990
Days to decision	87 days
Third-party review	No

**APPLICANT**

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Company	<b>Fukuda Denshi USA, Inc.</b>
Location	Mchenry, IL, US
Contact	ROBERT J STEURER
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/k903704/>; 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