

**K971131 FUKUDA DENSHI MODEL DS-5100E PORTABLE  
PATIENT MONITOR**Oct 3, 1997  
190 days to decisionK971131 · Product code: **DSI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k971131/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Mar 27, 1997
Decision date	Oct 3, 1997
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fukuda Denshi USA, Inc.</b>
Location	Mchenry, IL, US
Contact	DAVID J GERAGHTY
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/k971131/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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