

**K964187 FUKADA DENSHI DYNASCOPE MODEL DS-5300  
PATIENT MONITOR**May 1, 1997  
192 days to decisionK964187 · Product code: **DSI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k964187/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Oct 21, 1996
Decision date	May 1, 1997
Days to decision	192 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	SUSAN D GOLDSTEIN-FALK
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/k964187/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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