

**K081891 FUKUDA DENSHI DYNASCOPE MODEL  
DS-7000/7000M PATIENT MONITOR**Aug 29, 2008  
58 days to decisionK081891 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k081891/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jul 2, 2008
Decision date	Aug 29, 2008
Days to decision	58 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/k081891/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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