K081891 FUKUDA DENSHI DYNASCOPE MODEL DS-7000/7000M PATIENT MONITOR

CLEARED

Aug 29, 2008
58 days to decision

K081891 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k081891/

SUBMISSION DETAILS

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

Company	**Fukuda Denshi USA, Inc.**
Location	Mchenry, IL, US
Contact	SUSAN D GOLDSTEIN-FALK
510(k) history	68 submissions · 68 cleared · 1984-2018