FDA 510(k) Premarket Notification

CLEARED

K033711 FUKUDA DENSHI DYNASCOPE MODEL DS-5000 CENTRAL TELEMETRY SYSTEM

Jun 3, 2004
190 days to decision

K033711 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k033711/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Nov 26, 2003
Decision date	Jun 3, 2004
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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