FDA 510(k) Premarket Notification

K103134 FUKUDA DENSHI

CLEARED

Mar 11, 2011
137 days to decision

K103134 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k103134/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Oct 25, 2010
Decision date	Mar 11, 2011
Days to decision	137 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k103134/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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