FDA 510(k) Premarket Notification

CLEARED

K134046 FUKUDA DENSHI DYNASCOPE MODEL DS-8100N/8100M PATIENT MONITOR

Feb 12, 2015
408 days to decision

K134046 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k134046/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Dec 31, 2013
Decision date	Feb 12, 2015
Days to decision	408 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