FDA 510(k) Premarket Notification

CLEARED

K150030 Fukuda Denshi DynaScope Model DS-8000 Series Patient Monitor

Mar 16, 2015
67 days to decision

K150030 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k150030/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jan 8, 2015
Decision date	Mar 16, 2015
Days to decision	67 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