FDA 510(k) Premarket Notification

K141811 MORTARA MONITORING WAVEFORM VIEWER

CLEARED

Nov 19, 2014
135 days to decision

K141811 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k141811/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jul 7, 2014
Decision date	Nov 19, 2014
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mortara Instrument, Inc.**
Location	Walker, MI, US
Contact	AMY YANG
510(k) history	51 submissions · 51 cleared · 1983-2019