FDA 510(k) Premarket Notification

K143751 Visi Mobile Monitoring System

CLEARED

Jan 23, 2015
23 days to decision

K143751 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k143751/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Dec 31, 2014
Decision date	Jan 23, 2015
Days to decision	23 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Sotera Wireless, Inc.**
Location	San Diego, CA, US
Contact	Eben Gordon
510(k) history	9 submissions · 9 cleared · 2012-2018