FDA 510(k) Premarket Notification

K130709 VISI MOBILE MONITORING SYSTEM

CLEARED

Oct 7, 2013
206 days to decision

K130709 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k130709/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Mar 15, 2013
Decision date	Oct 7, 2013
Days to decision	206 days
Third-party review	No
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