

K142827 Visi Mobile Monitoring System, Visi Mobile Chest Sensor

Jul 20, 2015
293 days to decision

K142827 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k142827/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Sep 30, 2014
Decision date	Jul 20, 2015
Days to decision	293 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k142827/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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