

K180472 ViSi Mobile Monitoring SystemJun 19, 2018
117 days to decisionK180472 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k180472/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Feb 22, 2018
Decision date	Jun 19, 2018
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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