

**K133222 SAAD PATIENT MONITOR (SPM)**Aug 6, 2014  
292 days to decisionK133222 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k133222/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Oct 18, 2013
Decision date	Aug 6, 2014
Days to decision	292 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Hanin Medical Services Co., Ltd.</b>
Location	Monroe, CT, US
Contact	RAYMOND J KELLY
510(k) history	1 submissions · 1 cleared · 2014-2014

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133222/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 6, 2026