

**K101067 SURESIGNS VM4, SURESIGNS VM6, SURESIGNS VM8  
MODEL: 863063, 863064, 863065, 863066, 863068**May 7, 2010  
21 days to decisionK101067 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k101067/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Apr 16, 2010
Decision date	May 7, 2010
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Philips Medical Systems</b>
Location	Seattle, WA, US
Contact	PENG CUI
510(k) history	107 submissions · 105 cleared · 2002-2021

Philips Medical Systems is a Dutch multinational health technology company headquartered in Amsterdam with U.S. operations based in Seattle. The company evolved from a consumer electronics conglomerate founded in 1891 to a healthcare-focused organization. Philips Medical Systems has received FDA 510(k) clearances from total submissions between 2002 and 2021. The company's regulatory focus centered on Cardiovascular devices, which represented 79% of all submissions. This historical record reflects the company's significant presence in diagnostic ultrasound systems and pati...

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k101067/> 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 21, 2026