

**K173830 MAC VU360 Resting ECG Analysis System**Sep 18, 2018  
274 days to decisionK173830 · Product code: **DPS** · Cardiovascular  
Source: <https://www.510kdatabase.net/k173830/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Dec 18, 2017
Decision date	Sep 18, 2018
Days to decision	274 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Ge Medical Systems Information Technologies, Inc.</b>
Location	Milwaukee, WI, US
Contact	Marcella Entwisle
510(k) history	31 submissions · 31 cleared · 2010-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173830/> 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 May 26, 2026