

**K252840 M12 Telemetry System**May 29, 2026  
266 days to decisionK252840 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k252840/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Sep 5, 2025
Decision date	May 29, 2026
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Global Instrumentation, LLC</b>
Location	Manlius, NY, US
Contact	Craig Sellers
510(k) history	5 submissions · 5 cleared · 2005-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252840/> Data sourced from FDA 510(k) public records (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. - Generated June 5, 2026