FDA 510(k) Premarket Notification

K252840 M12 Telemetry System

CLEARED

May 29, 2026
266 days to decision

K252840 · 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	**Global Instrumentation, LLC**
Location	Manlius, NY, US
Contact	Craig Sellers
510(k) history	5 submissions · 5 cleared · 2005-2026