May 29, 2026

Global Instrumentation, LLC
Doug Linquest
Vice President Marketing & Business Development
7010 Fly Road STE 5
East Syracuse, New York 13057

Re: K252840
Trade/Device Name: M12 Telemetry System
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II
Product Code: MHX
Dated: April 30, 2026
Received: April 30, 2026

Dear Doug Linquest:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See

the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JENNIFER W. SHIH -S

Jennifer Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252840

Device Name
M12 Telemetry System

Indications for Use *(Describe)*
The M12 Telemetry System is intended for use by trained clinical research healthcare professionals for the purpose of centralized monitoring of adult and adolescent patients (11 to 17 years) participating in clinical studies within clinical research facilities. Centralized monitoring involves the display and management of data from networked patient telemetry transmitters including the annunciation of visual and audible physiologic parameter alarms at a central monitoring workstation.

The M12 Telemetry System with resting 12-lead ECG is intended for the production and interpretation of diagnostic electrocardiograms for adult and adolescent patients when connected to a transmitter with 12-Lead ECG monitoring enabled.

The M12RT Telemetry Transmitter is intended for use with the M12A Telemetry Central Station to monitor ECG on ambulatory and non-ambulatory adult and adolescent patients using wireless communication over the M12 telemetry network.

The M12RT Telemetry Transmitter can deliver ECG data using a 10-lead cable.

The M12 Telemetry System is not intended for general patient monitoring (e.g., hospitals, intensive care units, operating room, and other healthcare facilities except for clinical research).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

Prepared in accordance with 21 CFR 807.92

1. Submitter Information

Submitter Name: Global Instrumentation, LLC

Address: 7010 Fly Road STE 5 East Syracuse NY 13057 United States

Contact Person: Doug Linquest; Vice President Marketing & Business Development

Phone Number: 760-960-0869

Email Address: doug.linquest@gi-med.com

Date Prepared: May 29, 2026

2. Device Identification

Proprietary Name: M12 Telemetry System

Common/Usual Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)

Classification Name: Monitor, Physiological, Patient(With Arrhythmia Detection Or Alarms

Regulation Number: 21 CFR 870.1025

Product Code: MHX

Device Class: Class II

Review Panel: Cardiovascular

3. Predicate Device(s)

Predicate Device Name: Infinity Central Station Wide, Infinity M300, Infinity M300+

Manufacturer: Draeger Medical Systems

510(k) Number: K2314774

4. Device Description

The M12 Telemetry System is a central monitoring system capable of real-time display and storage of ECG physiologic patient data and alarm annunciation for networked devices including ambulatory wireless telemetry transmitters. The system is comprised of the M12A Central Station, M12A Review & Admin Station, M12A Telemetry Server, and the M12RT Telemetry Transmitter.

The M12A Central Station can perform telemetry monitoring using the M12RT Telemetry Transmitter integrated with a wireless network infrastructure installed in the clinical research healthcare organization's facility.

The systems intended functions include:

- Real-time 10-wire (12-lead) ECG signal display
- Real-time analysis program runs on three selectable ECG channels
- Automatic monitoring of arrhythmias including display of a single channel waveform for each patient
- Visual and audible alarms of events, arrhythmias, and set parameters with adjustable priorities
- Graphical trend review
- ECG signal data storage with full-disclosure storage and review

Through telemetry, patients using ambulatory transmitters are monitored while moving in a designated area. To guarantee proper signal transmission in various situations, install an antenna network as per facility requirements.

M12A Central Station may be set up in a variety of system configurations to support the acquisition and storage of real-time patient monitoring data.

Optional data storage is available for on or off premise storage. This increases storage capacity as well as allows storage to duplicate data disks when continuous and complete ECG capture is critical. This is valuable for institutions that collect ECG data for research purposes.

Networked printers are used for automatic or manual printouts of 12-lead ECG, ECG rhythm, and reports.

The M12A Central Station provides the means for users to manage patient records with associated patient demographics and assign each to a particular M12R Telemetry Transmitter for obtaining cardiac physiological information. Physiological data obtained from the telemetry devices are viewable and stored continuously up to 96 hours. Alarm monitoring and management, including definition of alarm limits, as well as data trending and reporting are available. Full disclosure supports review of the data on a particular patient including review of 12-lead ECG waveforms and other data and waveforms for obtained parameters.

5. Intended Use / Indications for Use

The M12 Telemetry System is intended for use by trained clinical research healthcare professionals for the purpose of centralized monitoring of adult and adolescent patients (11 to 17 years) participating in clinical studies within clinical research facilities. Centralized monitoring involves the display and management of data from networked patient telemetry transmitters including the annunciation of visual and audible physiologic parameter alarms at a central monitoring workstation.

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6. Comparison of Technological Characteristics

The intended use, principles of operation, and technological characteristics are substantially equivalent to the referenced predicate device.

Technological differences between the subject and predicate device include:

Physiological Parameters Monitored
– Subject device includes ECG
– Predicate includes ECG & pulse oximetry (SpO2)

ECG lead configuration options
– Subject device utilizes a 10-leadwire patient cable to provide 12-lead ECG with leads - I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
– Predicate offers leadwire patient cable confirgurations of 3-wire (leads I, II, III), 5-wire (leads I, II, III, aVL, aVR, aVF, V), 6-wire (I, II, III, aVL, aVR, aVF, V, V+), and 6-wire TrustST for 12L ECG (I, II, III, aVL, aVR, aVF, dV1, V2, dV3, dV4, V5, dV6)

Monitoring capacity
– The subject system supports up to 64 patients on continuous telemetry monitoring at central station
– Predicate device supports up to 32 patients on continuous telemetry monitoring at central station

Battery Type
– Subject device uses AA (LR6) disposable batteries with lithium polymer internal battery to support battery swap
– Predicate uses a custom lithium-ion battery pack

7. Performance Testing

The following non-clinical testing was performed to demonstrate the safety and effectiveness of the subject device as compared to the predicate.

Electrical Safety, EMC, Wireless Testing

- IEC 60601-1 Electrical Safety

- IEC 60601-1-2 EMC Testing

- IEC 62133

- UL 1642

- AAMI TIR 69

The technological characteristics of the subject device have been tested for function and performance characterization in accordance with the following standards:

- IEC 60601-2-27

- ANSI/AAMI EC53

- ANSI/AAMI EC57

- EN 60601-1-8

- IEC 60601-2-25

Software Validation

- IEC 62304

Biocompatibility Testing

- Cytotoxicity Testing (MEM Elution) – ISO 10933-5

- Sensitization Testing (Guinea Pig Maximization) – ISO 10933-10

- Irritation Testing (Intracutaneous Irritation) – ISO 10933-23

Packaging and Transit

- ASTM D4169-22

Safety & Essential Performance - Usability

- IEC 60601-1-6

- IEC 62366-1

Conclusion

To establish substantial equivalence of the M12 Telemetry System, Global Instrumentation conducted functional and system level testing to validate the performance of the devices. The results of the bench testing show that the subject device meets its safety, performance, and accuracy specification, and is substantially equivalent to the predicate device.