January 16, 2026

Baxter Healthcare Corp./Excel Medical
Gena Wolfe
Manager, Regulatory Affairs
7111 Fairway Dr. Suite 205
Palm Beach Gardens, Florida 33418

Re: K250135
Trade/Device Name: WAVE Clinical Platform (2.0.000)
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: January 9, 2026
Received: January 14, 2026

Dear Gena Wolfe:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

STEPHEN C. BROWNING -S

LCDR Stephen Browning
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.

Submission Number *(if known)*

K250135

Device Name

WAVE Clinical Platform (2.0.000)

Indications for Use *(Describe)*

The WAVE Clinical Platform is software intended to route, store, and display data, alarms, results and diagnostic information from medical devices, Electronic Medical Records (EMR), and Clinical Information Systems (CIS). The WAVE Clinical Platform is a remote monitoring platform that displays physiological data, waveforms, alarms, results, diagnostic and operational information routed through the platform from devices and systems using supported protocols. The WAVE Clinical Platform is intended for use in hospital and hospital type environments or where clinical consultations are needed. The WAVE Clinical Platform is intended to be used by healthcare professionals for the following purposes:

• To remotely consult regarding patients' conditions and statuses;
• To remotely review other standard or critical patient and operational data, waveforms, alarms, and results to utilize this information to aid in clinical decisions.

Warning: The WAVE Clinical Platform is intended to supplement and not replace any part of the hospital's device monitoring or electronic data management systems. Do not rely on the WAVE Clinical Platform product as the sole source of alarms.

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.

510(k) Summary

January 6, 2026

OWNER:

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CONTACT PERSON:

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Care and Connectivity Solutions Division
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Telephone: (816) 863-3370

IDENTIFICATION OF THE DEVICE:

Common Name: "WAVE Clinical Platform; Data Management, Visualization and Clinical Decision Support Software"
Trade/Device Name: "WAVE Clinical Platform"
Classification Panel: Cardiovascular
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI

Table 1. Version Number(s) for WAVE Clinical Platform

Version Number	Name	Proposed Device 510k
2.0.000	WAVE Clinical Platform	K250135

PREDICATE DEVICE:

Table 2. Predicate Device(s)

Device	Company	Predicate 510(k)	Clearance Date
Version 1.0 WAVE Clinical Platform	EXCEL Medical	K171056	January 2018

DESCRIPTION OF THE DEVICE:

The WAVE Clinical Platform is a remote monitoring platform that displays physiological data, waveforms, alarms, results, diagnostic and operational information routed through the platform from devices and systems using supported protocols. The WAVE Clinical Platform can also route and forward this data to third party systems.

The WAVE Clinical Platform can utilize the hospital's existing network and hardware for installation and display on any device that is web-enabled. The WAVE Clinical Platform does not control any of the medical devices or systems it is connected with.

Medical devices and information systems are the predominant sources of data used in the WAVE applications. Data sources such as multi-parameter patient monitors, telemetry transmitters, vital sign monitors, ventilators, anesthesia machines, oximeters, hemodynamic monitors, oxygen saturation monitors, capnography monitors, sedation monitors, nurse call systems, smartphone mobile applications, smart beds, precision locating systems, cameras, variability indexes, hospital information systems, clinical information systems, electronic medical record systems, lab information systems, order systems, fluid delivery systems, medication delivery systems, infusion systems, clinical deterioration algorithm derivatives, gateway servers, etc. provide digital outputs acquired by WAVE and by Medical Device Data Systems that then transfer the data to WAVE.

INTENDED USE:

The WAVE Clinical Platform is software intended to route, store, and display data, alarms, results and diagnostic information from medical devices, Electronic Medical Records (EMR), and Clinical Information Systems (CIS). The WAVE Clinical Platform is a remote monitoring platform that displays physiological data, waveforms, alarms, results, diagnostic and operational information routed through the platform from devices and systems using supported protocols. The WAVE Clinical Platform is intended for use in hospital and hospital type environments or where clinical consultations are needed. The WAVE Clinical Platform is intended to be used by healthcare professionals for the following purposes:

- To remotely consult regarding patients' conditions and statuses;
- To remotely review other standard or critical patient and operational data, waveforms, alarms, and results to utilize this information to aid in clinical decisions.

Warning: The WAVE Clinical Platform is intended to supplement and not replace any part of the hospital's device monitoring or electronic data management systems. Do not rely on the WAVE Clinical Platform product as the sole source of alarms.

Table 3. Device Comparison

Features	Primary Predicate Device Wave Clinical Platform cleared under K171056	Proposed Device WAVE Clinical Platform 2.0 K250135	Assessment of Differences
Intended Use	The WAVE Clinical Platform is software intended to route, store, and display data, alarms, results and diagnostic information from medical devices, Electronic Medical Records (EMR), and Clinical Information Systems (CIS). The WAVE Clinical Platform is a remote monitoring platform that displays physiologic data, waveforms, alarms, results and diagnostic information routed through the platform from supported devices and systems. The WAVE Clinical Platform is intended for use in hospital or hospital type environments. The WAVE Clinical Platform is intended to be used by healthcare professionals for the following purposes: • To remotely consult regarding patients' statuses; • To remotely review other standard or critical near real-time patient data, waveforms, alarms, and results in order to utilize this information to aid in clinical decisions. Warning: The WAVE Clinical Platform is intended to supplement and not replace any part of the hospital's device monitoring or electronic data management systems. Do not rely on the WAVE Clinical Platform product as the sole source of alarms.	The WAVE Clinical Platform is software intended to route, store, and display data, alarms, results and diagnostic information from medical devices, Electronic Medical Records (EMR), and Clinical Information Systems (CIS). The WAVE Clinical Platform is a remote monitoring platform that displays physiological data, waveforms, alarms, results, diagnostic and operational information routed through the platform from devices and systems using supported protocols. The WAVE Clinical Platform is intended for use in hospital and hospital type environments or where clinical consultations are needed. The WAVE Clinical Platform is intended to be used by healthcare professionals for the following purposes: • To remotely consult regarding patients' conditions and statuses; • To remotely review other standard or critical patient and operational data, waveforms, alarms, and results to utilize this information to aid in clinical decisions **Warning**: The WAVE Clinical Platform is intended to supplement and not replace any part of the hospital's device monitoring or electronic data management systems. Do not rely on the WAVE Clinical Platform product as the sole source of alarms.	Same

Table 3. Device Comparison

Features	Primary Predicate Device Wave Clinical Platform cleared under K171056	Proposed Device WAVE Clinical Platform 2.0 K250135	Assessment of Differences
Indications for Use	The WAVE Clinical Platform is a remote monitoring platform that displays physiologic data, waveforms, alarms, results and diagnostic information routed through the WAVE Clinical Platform from supported devices and systems. The WAVE Clinical Platform is intended for use in hospital or hospital type environments. The WAVE Clinical Platform is intended to be used by healthcare professionals for the following purposes: - To remotely consult regarding patients' statuses; - To remotely review other standard or critical **near real-time** patient data, waveforms, alarms, and results in order to utilize this information to aid in clinical decisions. Warning: The WAVE Clinical Platform is intended to supplement and not to replace any part of the hospital's device monitoring or electronic data management systems. Do not rely on the WAVE Clinical Platform product as the sole source of alarms.	The WAVE Clinical Platform is a remote monitoring platform that displays physiologic data, waveforms, alarms, results and diagnostic information routed through the WAVE Clinical Platform from supported devices and systems. The WAVE Clinical Platform is intended for use in hospital or hospital type environments. The WAVE Clinical Platform is intended to be used by healthcare professionals for the following purposes: - To remotely consult regarding patients' conditions and statuses; - To remotely review other standard or critical patient data, waveforms, alarms, and results in order to utilize this information to aid in clinical decisions. Warning: The WAVE Clinical Platform is intended to supplement and not to replace any part of the hospital's device monitoring or electronic data management systems. Do not rely on the WAVE Clinical Platform product as the sole source of alarms.	Primary predicate stated "near real-time patient data". This terminology was removed from proposed device submission at request of FDA reviewer.

Table 3. Device Comparison

Features	Primary Predicate Device Wave Clinical Platform cleared under K171056	Proposed Device WAVE Clinical Platform 2.0 K250135	Assessment of Differences
Sterile	N/A; software	N/A; software	N/A; software
Non-Pyrogenic	N/A; software	N/A; software	N/A; software
Single Use	Yes	Yes	Same
Materials (List components in this column which are relevant to the type of contact, e.g. fluid path, direct contact with blood, patient)	N/A; software	N/A; software	N/A; software
Device Regulatory Classification	21 CFR 870.2300; Cardiac monitor (including cardiotachometer and rate alarm)	21 CFR 870.2300; Cardiac monitor (including cardiotachometer and rate alarm)	Same
Other Technology Used	Standard computers, network, and WIFI technology	Standard computers, network, and WIFI technology	Same
Host server	Uses hospital's existing server hardware or server pre-loaded with the WAVE Clinical Platform software and off-the-shelf operating system	Uses hospital's existing server hardware or server pre-loaded with the WAVE Clinical Platform software and off-the-shelf operating system	Same
Ability to View Data and Serves As Secondary Means Of Annunciating Patient Events	Yes	Yes	Same
Synopsis of Functionality	Store, route and display patient monitor, EMR and CIS data, alarms, and smart alarms remotely to aid in clinical decisions and deliver patient care in a timely manner	Store, route and display patient monitor, EMR and CIS data, alarms, and smart alarms remotely to aid in clinical decisions and deliver patient care in a timely manner	Same
Target Population/ Demographics	In-hospital patients that have physiological sensors attached.	In-hospital patients that have physiological sensors attached.	Same

Table 3. Device Comparison

Applications	PatientWatch TeleTrend	PatientWatch TeleTrend AlarmView AlarmNotification	WAVE 2.0.000 has an additional two applications for customer interface improvements. Additional functionality in the subject device does not affect the intended use and fundamental scientific technology.

DISCUSSION OF NONCLINICAL TESTS:

Non-Performance Data:

The changes since the last 510(k) approval were evaluated to ensure that the change did not impact the integrity or performance of the product or raise different questions of safety and effectiveness.

Non-Performance testing was conducted on the WAVE Clinical Platform 2.0.000 to evaluate the functional performance of the device. Testing involved system level tests, performance tests and safety testing based on hazard analysis. Cybersecurity issues have been addressed and are included within the eSTAR attachments. Detailed summary information regarding the non-performance testing is supplied in Performance Testing: Bench and/or Performance Testing and the Software Documentation: Software Verification and Validation Testing within the eSTAR submission documentation. In addition to the verification and validation testing activities executed by Excel Medical Electronics, LLC to establish the performance and functionality of the WAVE Clinical Platform and the predicate device, several standards were utilized:

- **ISO 14971** – Medical Devices – Application of Risk Management to Medical Devices
- **IEC 62366-1** - Medical devices - Part 1: Application of usability engineering to medical devices
- **IEC 60601-8** - Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

Baxter/Excel Medical Electronics, LLC referred to the following documents:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff
- Guidance for Industry – Applying Human Factors and Usability Engineering to Optimize Medical Device Design

- Guidance for Industry – Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software

- Guidance for Industry - Off the Shelf Software Use in Medical Devices

Biocompatibility:

N/A

CONCLUSION:

The WAVE Clinical Platform 2.0.000 510(k) package and results on non-clinical testing demonstrates the WAVE Clinical Platform 2.0.000 is substantially equivalent and performs comparably to the predicate device, WAVE Clinical Platform that is currently marketed for the same intended use.