510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K202101

B Applicant

Accriva Diagnostics, Inc.

C Proprietary and Established Names

GEM Hemochron 100 System, GEM Hemochron 100 Activated Clotting Time Plus Test (ACT+), GEM Hemochron 100 Low Range Activated Clotting Time Test (ACT-LR), directCHECK ACT+ Whole Blood Control, Level 1 and Level 2, directCHECK ACT-LR Whole Blood Control, Level 1 and Level 2

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JPA	Class II	21 CFR 864.5425 - Multipurpose System For In Vitro Coagulation Studies	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Activated Clotting Time (ACT+ and ACT-LR)

C Type of Test:

Quantitative test for ACT+ and ACT-LR measurands

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The GEM® Hemochron™ 100 System is a battery-operated portable instrument that performs individual in vitro quantitative coagulation tests on fresh whole blood. The system is intended to be used with test cartridges available from the manufacturer and include tests for Activated Clotting Time (ACT+) and Low Range Activated Clotting Time (ACT-LR). The system is intended for use only in point-of-care settings for patients aged 18 years and above.

The GEM® Hemochron™ 100 ACT+ (Activated Clotting Time Plus) test is a quantitative assay for monitoring anticoagulation with moderate to high unfractionated heparin (UFH) doses in fresh whole blood samples. This test is intended for monitoring UFH administered during cardiovascular surgery and cardiac ablation procedures. The GEM® Hemochron™ 100 ACT+ demonstrates linear correlation to the anticoagulation effects of UHF concentrations of 1.0 to 6.0 units/mL.

The GEM® Hemochron™ 100 ACT-LR (Low Range Activated Clotting Time) test is a quantitative assay for monitoring anticoagulation with low to moderate unfractionated heparin (UFH) doses in fresh whole blood samples. This test is intended for monitoring UFH administered during extracorporeal life support and cardiology procedures. The GEM® Hemochron™ 100 ACT-LR test demonstrates linear correlation to the anticoagulation effects of UFH concentrations up to 2.5 units/mL.

For in vitro diagnostic use. For Professional Use, Rx Only.

The GEM® Hemochron™ 100 ACT+ (Activated Clotting Time Plus) test is a quantitative assay for monitoring anticoagulation with moderate to high unfractionated heparin (UFH) doses in fresh whole blood samples. This test is intended for monitoring UFH administered during cardiovascular surgery and cardiac ablation procedures. The GEM® Hemochron™ 100 ACT+ demonstrates linear correlation to the anticoagulation effects of UFH concentrations of 1.0 to 6.0 units/mL.

The GEM® Hemochron™ 100 ACT+ test can be performed on the GEM® Hemochron™ 100 System and any model of Hemochron™ Signature Series device. Each instrument is portable, which allows testing at point-of-care or in a satellite or central laboratory.

For in vitro diagnostic use. For Professional Use, Rx Only.

The GEM® Hemochron™ 100 ACT-LR (Low Range Activated Clotting Time) test is a quantitative assay for monitoring anticoagulation with low to moderate unfractionated heparin (UFH) doses in fresh whole blood samples. This test is intended for monitoring UFH administered during extracorporeal life support and cardiology procedures. The GEM®

Hemochron™ 100 ACT-LR test demonstrates linear correlation to the anticoagulation effects of UFH concentrations up to 2.5 units/mL.

The GEM Hemochron 100 ACT-LR test can be performed on the GEM® Hemochron™ 100 system and any model of Hemochron™ Signature Series device. Instruments are portable, which allows testing at point-of-care or in a satellite or central laboratory.

For in vitro diagnostic use. For Professional Use, Rx Only.

The directCHECK™ Whole Blood Quality Controls are dried whole blood preparations which have been assayed and are intended to be used to perform quality control assays using the Hemochron™ test cartridges.

For in vitro Diagnostic Use. For Professional Use, Rx Only.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

Not applicable

IV Device/System Characteristics:

A Device Description:

The GEM Hemochron 100 system is a battery-operated, point-of-care coagulation analyzer that represents the next generation platform of the predicate Hemochron™ Signature Elite microcoagulation system. Like the Hemochron Signature Elite instrument, the GEM Hemochron 100 is designed to be used with ACT+ and ACT-LR cuvettes in vitro diagnostic tests designed to determine the Activated Clotting Time (ACT) of fresh whole blood samples at both low (ACT-LR) and high (ACT+) levels of heparin doses. The GEM Hemochron 100 employs the same fundamental opto-mechanical clot detection technology and the same analytical algorithms used by the predicate device for calculating test results. The single-use test cartridges for Activated Whole Blood Clotting Time Plus (ACT+) or Low Range ACT (ACT-LR) assays are identical to the cartridges used by the predicate analyzer. Whole Blood Controls used on the GEM Hemochron 100 system are identical to those used on the Hemochron™ Signature Elite. The system is intended for use only in clinical settings requiring point-of-care testing. ACT results for patient blood samples or liquid control material are displayed as ACT Celite-equivalent values (CEV) in seconds, for both test types.

The analyzer contains a test chamber which warms a test cuvette to the required temperature, and it performs all operations to measure the clotting time of a whole blood sample after it is placed in the test cuvette and the test is started by the operator. The user interface includes a color touch screen that displays various action keys and an external barcode scanner for reading Operator

identification number (OID), Patient identification (PID) number and lot numbers and expiration dates of liquid quality controls (QC). The operator uses the touch screen to select a command, set software configurations or enter information.

The GEM Hemochron 100 system is POCT1-A2 compliant and has Wi-Fi and Ethernet networking capability. It has increased storage for 10,000 patient and QC records. ACT+ and ACT-LR cartridge labels are modified to include a 2D barcode that identifies test type, lot number and expiry date, which is readable by the internal camera. Quality control features such as designation of QC levels, tagging of test results with date and time, and entry of OID and PID numbers are included and are similar to the predicate device.

The device contains an 802.11 interface which supports WPA2 encryption as well as EAP authentication framework. The device is able to connect to a Wireless Local Area Network (WLAN) via 802.11 b/g/n connections at 2.4 and 5 GHz. The communications interfaces supported by the device are utilized to configure or update the device software by supervisory staff before deployment to the intended use environment and in the reporting of test results to the Laboratory or Hospital Information Systems by the clinical operators at the point of care. Test results are used directly at the point of care in aiding medical decision making, and the device's intended use is not reliant on the device's ability to transmit the information to the LIS/HIS.

Length – 7.4 inches; Width – 4.0 inches; Depth – 2.0 inches

Table 1: Instrument Components

No.	Component	Description
1	Ethernet Port	Connector port for the Ethernet cable when connecting an instrument to a Local Area Network (LAN).
2	Power Supply Port	Connector port for the power supply cable when charging the battery.
3	Power Button	Used to power the instrument on and off. This button is also used to put the instrument into sleep mode and wake the instrument from sleep mode.
4	Barcode Scanner	Used for scanning barcodes to enter Operator ID (OID), Patient ID (PID), and Liquid Quality Control (LQC) lot information. Supported barcode formats: Aztec, Code 39, Code 128, Micro PDF417, PDF417, QR. **NOTE:** This scanner does not scan the barcode on the cartridge.
5	Color Touch Screen (Display Screen)	The interface that *Operators* use to operate the instrument.
6	Cartridge Insertion Port	The port into which a cartridge is inserted.

Activated Clotting Time Plus (ACT+) Test and Low Range Activated Clotting Time (ACT-LR) Test Marketed with GEM Hemochron 100

Two types of test cartridges (cuvettes) are available with the GEM Hemochron 100. Each type of cartridge is intended for one type of test.

- *GEM Hemochron 100 Activated Clotting Time Plus (ACT+) Test*

  The GEM Hemochron 100 ACT+ test is a quantitative assay for monitoring anticoagulation with moderate to high unfractionated heparin (UFH) doses in fresh whole blood samples. This test is intended for monitoring UFH administered during cardiovascular surgery and cardiac ablation procedures. The GEM Hemochron 100 ACT+ demonstrates sensitivity to UFH concentrations of 1.0 to 6.0 units/mL. The GEM Hemochron 100 ACT+ test can be performed on the GEM Hemochron 100 System and any model of Hemochron Signature Series device.

  GEM Hemochron 100 ACT+ cartridges are single-use disposable test devices with a well for application of liquid QC and whole blood samples. When a liquid QC or patient test is requested, the instrument prompts the Operator to insert a cartridge into the instrument. After the instrument warms the cartridge, it prompts the Operator to apply the sample into the sample well of the cartridge.

  The ACT+ test cartridge is a self-contained disposable test chamber preloaded with a dried preparation of silica, kaolin, phospholipid, stabilizers, and buffers that provide maximum activation as defined by clinical practice guidelines. Each cartridge is sealed in a foil pouch labeled with lot number and expiry date.

  Reagents in GEM Hemochron 100 ACT+ cartridges are identical in composition to those in the predicate Hemochron ACT+ cuvettes. A 2D barcode added to the cartridge label identifies the test type, lot number and expiry date. This information is automatically read by the internal camera.

- *GEM Hemochron 100 Low Range Activated Clotting Time (ACT-LR) Test*

  The GEM Hemochron 100 ACT-LR (Low Range Activated Clotting Time) test is a quantitative assay for monitoring anticoagulation with low to moderate unfractionated heparin (UFH) doses in fresh whole blood samples. This test is intended for monitoring UFH administered during extracorporeal life support, and cardiology procedures. The GEM Hemochron 100 ACT-LR test demonstrates sensitivity to UFH concentrations up to 2.5 units/mL. The GEM Hemochron 100 ACT-LR test can be performed on the GEM Hemochron 100 system and any model of Hemochron Signature Series device.

  GEM Hemochron 100 cartridges are single-use disposable test devices with wells for application of samples. When a patient test or an LQC test is requested, the instrument prompts the Operator to insert a cartridge into the instrument. After the instrument warms the cartridge, it prompts the Operator to apply the sample into the sample well of the cartridge.

Each GEM Hemochron 100 ACT-LR cartridge is sealed in a foil pouch labeled with lot number and expiry date. The cartridge is a self-contained disposable test chamber preloaded with a dried preparation of Celite and silicon dioxide activators, potato dextrin, stabilizers, and buffers to provide maximum activation as defined by clinical practice guidelines.

Reagents in GEM Hemochron 100 ACT-LR cartridges are identical in composition to those in the predicate Hemochron ACT-LR cuvettes. A 2D barcode added to the cartridge label identifies the test type, lot number and expiry date. This information is automatically read by a new internal camera.

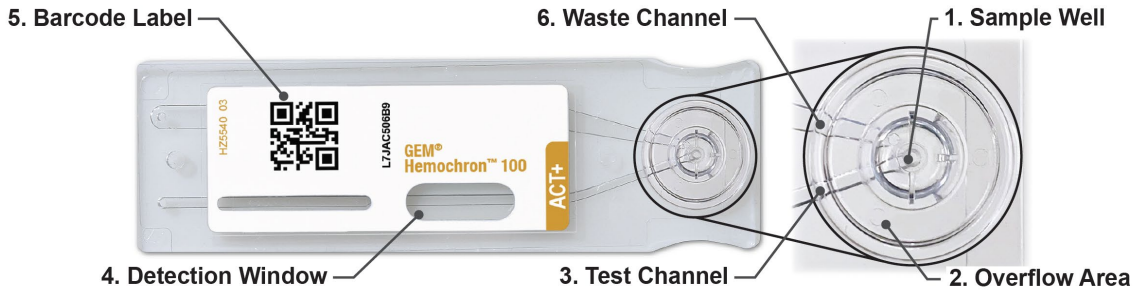

Table 2: Cartridge Components

No.	Component	Description
1	Sample Well	The location where the sample is applied.
2	Overflow Area	Excess sample flows into this area and then into the waste channel.
3	Test Channel	The instrument vacuum pump draws the sample into the test channel where it is mixed with reagent.
4	Detection Window	An internal camera analyzes the sample through the detection window.
5	Barcode Label	The barcode label contains the cartridge lot number, expiration date, and test type. When a cartridge is inserted into the cartridge insertion port, the instrument reads this information. Information on the label is also human-readable.
6	Waste Channel	The instrument vacuum pump draws excess sample into the waste channel. This ensures that the sample volume is correct.

directCHECK Whole Blood Controls Marketed with GEM Hemochron 100

The directCHECK Whole Blood Quality Controls are dried whole blood preparations which have been assayed and are intended to be used to perform quality control assays using the Hemochron test cartridges. Two levels of control are available for each type of activated clotting time test.

- directCHECK ACT+ Whole Blood Control (Normal)
- directCHECK ACT+ Whole Blood Control (Abnormal)
- directCHECK ACT-LR Whole Blood Control (Normal)
- directCHECK ACT-LR Whole Blood Control (Abnormal)

Description of Device Changes:

The design of the subject device upgrades the user interface, expands data storage capacity, adds

Wi-Fi networking, and adds new and/or enhanced functionality. Enhancements in the GEM Hemochron 100 system when compared to the predicate include:

- Color touchscreen
- 2D barcoded cartridges labels providing assay type, lot number and expiry date
- Camera to monitor clot detection and decode 2D barcodes on cartridge labels
- Expanded storage for OID and PID numbers, and patient and QC records
- Upgraded the OS from that of the predicate device to Android Nougat
- Improved communication interface with addition of Wi-Fi networking

B Principle of Operation:

The GEM Hemochron 100 system measures whole blood ACT using single-use disposable cartridges. Each cartridge contains all of the reagents necessary for a specified test. The Operator inserts a cartridge into the instrument where the internal camera reads the information from a barcode. Once the cartridge is warmed to the specified temperature, the instrument prompts the Operator to add a blood sample into the cartridge sample well. Testing is initiated by pressing the Start Test icon on the touch screen. When the test begins, the instrument draws blood from the sample well into the test channel of the cartridge, where the blood is mixed with the reagent. The remaining blood sample, not needed for testing, is automatically drawn out of the sample well and into an enclosed waste channel in the cartridge.

The instrument mixes the sample and reagent by pumping the mixture back and forth at a predetermined rate within the test channel at a specified temperature. The optical system (internal camera system) monitors the motion of the sample and reagent in the test channel. As the blood begins to clot, the flow of the blood sample within the test channel is impeded, which reduces its rate of flow. Flow reduction below a predetermined value signals to the instrument that a fibrin clot has formed. An internal timer measures the elapsed time between the start of the test and the clot formation. During the test, the elapsed time is displayed as ACT Celite-equivalent values (CEV) in seconds. Upon completion of the test, the CEV is displayed and recorded by the instrument.

Test results (patient tests, EQC tests, and LQC tests) are saved in the instrument internal database. As many as 10,000 test results can be saved on the instrument. The results can also be sent to a computer (HIS/LIS) on the network via the GEMweb Plus 500 middleware.

GEMweb Plus 500 is middleware compatible to communicate with the GEM Hemochron 100 system. It allows networking of a group of analyzers and provides remote access for managing analytical devices and operator profiles. More specifically, the middleware is limited to sending data on operator credentials, liquid quality control lot information, and test cartridge lot information. In addition, the middleware can receive and relay test results from the GEM Hemochron 100 instrument. The GEMweb Plus 500 middleware does not support software upgrades, control of critical device settings and configurations, and initiation of alarms.

The GEM Hemochron 100 system includes Windows-based centralized configuration manager (CCM) software that is substantially equivalent to Hemochron Configuration Manager (HCM) software included with the predicate. HCM was originally cleared with the Hemochron™

Signature Plus Whole Blood Microcoagulation System (K020798), which is the predicate for the Elite.

C Instrument Description Information:

1. Instrument Name:

   GEM Hemochron 100 System

2. Specimen Identification:

   Entry and control of Operator identification (OID) and Patient identification (PID) via touch screen and/or barcode scanning.

3. Specimen Sampling and Handling:

   Single-use disposable cartridges are used by the system. Each cartridge contains all of the reagents necessary for a specified test. The operator inserts a cartridge into the instrument where the internal camera reads the information from a barcode. Once the cartridge is warmed to the specified temperature, the instrument prompts the operator to add a blood sample into the cartridge sample well. Testing is initiated by pressing the Start Test icon on the touch screen. When the test begins, the instrument draws blood from the sample well into the test channel of the cartridge, where the blood is mixed with the reagent. The remaining blood sample, not needed for testing, is automatically drawn out of the sample well and into an enclosed waste channel in the cartridge.

4. Calibration:

   Not applicable

5. Quality Control:

   The GEM Hemochron 100 instrument should have two levels of quality control performed every 8 hours of operation. This requirement can be accomplished by conducting internal Electronic Quality Control (EQC) and/or external Liquid Quality Control (LQC) testing. Performance of the GEM Hemochron 100 test cartridges should be validated with two levels of LQC using directCHECK Quality Control products.

V *Substantial Equivalence Information:*

A Predicate Device Name(s):
Hemochron Signature Elite

B Predicate 510(k) Number(s):
K193041

C Comparison with Predicate(s):

Device & Predicate Device(s):	K202101	K193041
Device Trade Name	GEM Hemochron 100 System	Hemochron Signature Elite
General Device Characteristic Similarities		
Intended Use / Indications for Use	The GEM® Hemochron™ 100 System is a battery-operated portable instrument that performs individual in vitro quantitative coagulation tests on fresh whole blood. The system is intended to be used with test cartridges available from the manufacturer and include tests for Activated Clotting Time (ACT+) and Low Range Activated Clotting Time (ACT-LR). The system is intended for use only in point-of-care settings for patients aged 18 years and above. The GEM® Hemochron™ 100 ACT+ (Activated Clotting Time Plus) test is a quantitative assay for monitoring anticoagulation with moderate to high unfractionated heparin (UFH) doses in fresh whole blood samples. This test is intended for monitoring UFH administered during cardiovascular surgery and cardiac ablation procedures. The GEM® Hemochron™ 100 ACT+ demonstrates linear correlation to the anticoagulation effects of UHF concentrations of 1.0 to 6.0 units/mL. The GEM® Hemochron™ 100 ACT-LR (Low Range Activated Clotting Time) test is a quantitative assay for monitoring anticoagulation with low to moderate unfractionated heparin (UFH) doses in fresh whole blood samples. This test is intended for monitoring UFH administered during extracorporeal life support and cardiology procedures. The GEM® Hemochron™ 100 ACT-LR test demonstrates linear correlation to the anticoagulation effects of UFH concentrations up to 2.5 units/mL. For in vitro diagnostic use. For Professional Use, Rx Only.	The Hemochron™ Signature Elite Whole Blood Microcoagulation System is a battery-operated, hand-held instrument that performs individual point-of-care coagulation tests on fresh or citrated whole blood. These tests include: Activated Clotting Time (ACT+ and ACT-LR), Activated Partial Thromboplastin Time (APTT and APTT Citrate), and Prothrombin Time (PT and PT Citrate). The system is intended to be used with test cuvettes that are available from the manufacturer. For *in vitro* Diagnostic Use. For professional use. Rx only.
Assays Used	• Activated Clotting Time (ACT+ and ACT-LR) only	• Activated Clotting Time (ACT+ and ACT-LR); • Activated Partial Thromboplastin Time (APTT and APTT Citrate); • Prothrombin Time (PT and citrate-PT)
Sample Type	Fresh Whole Blood only	Fresh Whole Blood; Citrated Whole Blood
Reagents	Supplied in self-contained disposable cartridges (cuvettes)	Supplied in self-contained disposable cuvettes
Reported Results	ACT Celite-equivalent value (CEV) in seconds – ACT+ and ACT-LR	Celite ACT Equivalent Time – ACT+ and ACT-LR;

Device & Predicate Device(s):	K202101	K193041
		PT, citrate-PT (INR); Whole Blood Values – APTT, citrate-APTT, PT, citrate-PT; Plasma Equivalent (PE) Values – APTT, citrate-APTT, PT, citrate-PT
Results	Displayed on LCD screen	Same
Timing Range	0 seconds to 1005 seconds	Same
Operating Environment	15° to 30°C	Same
Clot Detection Method	Mechanical-optical clot detection	Same
Liquid QC Requirement	Two levels – performed as directed	Same
Electronic QC Requirement	Internal electronic QC	Same
Heater temperature control	Thermistor – modulated by software	Same
Power	Battery or AC operated	Same
General Device Characteristic Differences		
Operating System	Android 7.1 (Nougat)	IA188EBP
Software Version	1.1	2.4
Dimensions and weight	Depth 5 cm (2.0 inches) Width 10.2 cm (4.0 inches) Length 19 cm (7.4 inches) Weight 0.68 kg (1.5 pounds)	Depth 9.4 cm (3.7 inches) Width 19 cm (7.5 inches) Height 5 cm (2.0 inches) Weight 0.53 kg (1.2 pounds)
PC Connectivity	Wi-Fi and Ethernet ports; POCT1-A2	RS-232 and Ethernet ports; POCT1-A2
Data Storage Capacity	32- alphanumeric character OID / 32-character PID; 10,000 QC and test records	16-alphanumeric character OID / 20-character PID; 600 QC and test records
Optical Detection System	Internal camera	LED
User Interface	Touch screen and external barcode scanner	Keypad and external barcode scanner
OID / PID Input	Touch screen and external barcode scanner	Keypad
LQC Parameter Input	Touch screen and external barcode scanner	Keypad and external barcode scanner
Assay Parameter Input	Touch screen and external barcode scanner	Keypad and external barcode scanner
Supported Barcode Formats	Aztec, Code 39, Code 128, Micro PDF417, PDF417, QR	UPC/EAN, Code 128, Code 39, Trioptic Code 39, Code 93, Interleaved 2 of 5, Discrete 2 of 5, Codabar, and MSI Plessey
Incubation Warm Up Time	30 to 90 seconds	Up to 200 seconds

VI Standards/Guidance Documents Referenced:

The GEM Hemochron 100 System was successfully tested for electrical safety, emissions and immunity, and wireless performance to the following standards. Recognition number (RN) indicates that a standard is currently recognized by the FDA.

Electrical Safety:

IEC 61010-1, Safety requirements for electrical equipment for measurement, control and laboratory use. Part 1: General requirements. [RN:19-34]

IEC 61010-2-010, Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials.

IEC 61010-2-101, Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101. Particular requirements for in vitro diagnostic (IVD) medical equipment.

Emissions:

IEC 61326-1, Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General Requirements.

CISPR 11, Industrial, scientific and medical equipment – Radio- frequency disturbance characteristics – Limits and methods of measurement.

IEC 61000-3-2, Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions.

IEC 61000-3-3, Electromagnetic compatibility (EMC) – Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low – voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection.

FCC Part 15B §15.109, Radiated emission limits.

FCC Part 15B §15.107, Conducted limits.

Immunity (EMC):

IEC 60601-1-2, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Eletromagnetic Disturbances – Requirements and tests. [RN 19-8]

IEC 61000-4-2, Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test.

IEC 61000-4-3, Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test.

IEC 61000-4-4, Electromagnetic compatibility (EMC) – Part 4-4: Testing and measurement techniques – Electrical fast transient/burst immunity test.

IEC 61000-4-5, Electromagnetic compatibility (EMC) – Part 4-5: Testing and measurement techniques – Surge immunity test.

IEC 61000-4-6, Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radio- frequency fields.

IEC 61000-4-8, Electromagnetic compatibility (EMC) – Part 4-8: Testing and measurement techniques – Power frequency magnetic field immunity test.

IEC 61000-4-11, Electromagnetic compatibility (EMC) – Part 4-11: Testing and measurement techniques – Voltage dips, short interruptions and voltage variations immunity tests.

AIM 7351731, Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers. [RN 19-30]

ISO 14223, Radiofrequency identification of animals – Advanced transponders.

ISO/IEC 14443-3, Identification cards – Contactless integrated circuit cards – Proximity cards – Part 3: Initialization and anticollision.

ISO/IEC 14443-4, Cards and security devices for personal identification – Contactless proximity objects – Part 4: Transmission protocol.

ISO/IEC 15693-3, Identification cards – Contactless integrated circuit cards – Vicinity cards – Part 3: Anticollision and transmission protocol.

ISO/IEC 18000-3, Information technology – Radio frequency identification for item management – Part 3: Parameters for air interface communications at 13.56 MHz.

ISO/IEC 18000-7, Information technology – Radio frequency identification for item management – Part 7: Parameters for active air interface communications at 433 MHz

ISO/IEC 18000-63, Information technology – Radio frequency identification for item management – Part 63: Parameters for air interface communications at 860 MHz to 960 MHz Type C.

ISO/IEC 18000-4, Information technology – Radio frequency identification for item management – Part 4: Parameters for air interface communications at 2.45 GHz.

Wireless:

FCC Part 15C §15.247, Operation within the bands 902-928 MHz, 2400-2483.5 MHz, and 5725-5850 MHz.

FCC Part 15B §15.407, General technical requirements.

Other:

EN ISO 13485:2016, Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes, 03/01/2016

ANSI, AAMI, IEC 62304:2006/Al:2016, Medical Device Software - Software Life Cycle Processes [Including Amendment I (2016)], 01/14/2019. [RN:13-79]

ANSI, AAMI, IEC 62366-1:2015 Medical devices - Part I: Application of Usability Engineering to Medical Devices, 07/06/2020. [RN:5-129]

BSEN, ISO 14971:2012, Medical Devices: Application of Risk Management to Medical Devices, Second Edition, 07/31/2012

ANSI, UL UL2900-2-l 2017, Standard for Safety, Software Cybersecurity for Network Connectable Products, Part 2-1: Particular Requirements for Network-Connectable Components of Healthcare and Wellness Systems, First Edition, 06/17/2018

CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures, Third Edition, 10/01/2014. [RN:7-251]

CLSI EP09c, Measurement Procedure Comparison and Bias Estimation Using Patient Samples, Third Edition, 06/01/2018. [RN:7-296]

CLSI POCT01-A2, Point-of-Care Connectivity, Second Edition, 07/28/2006. [RN:13-14]

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Precision studies were conducted to determine whole blood precision and liquid quality control (directCHECK) reproducibility for ACT+ and ACT-LR cartridges on the GEM Hemochron 100 System.

LQC Reproducibility

In the LQC reproducibility study, samples were tested according to CLSI EP05-A3 with a test design of three sites, three instruments per site, five days, two runs per day, three replicates per run using one lot per cartridge type (ACT+ and ACT-LR) and a single lot of each control. For each level of LQC material, estimates of repeatability, between-run, between-day, between-instrument, between-site, and reproducibility were obtained and the summary data for this study is provided in the tables below. Overall, repeatability and reproducibility of tests run using directCHECK LQC for ACT+ and ACT-LR cartridges on the GEM Hemochron 100 met the acceptance criteria.

Table 3: LQC precision results – ACT+ directCHECK Level 1 (Normal)

N	Mean (sec.)	Repeatability		Between-Run		Between-Day		Between-Instrument		Between-Site		Reproducibility	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
270	162.6	12.2	7.5	2.5	1.5	0.0	0.0	2.0	1.2	3.9	2.4	13.2	8.1

Table 4: LQC precision results – ACT+ directCHECK Level 2 (Abnormal)

N	Mean (sec.)	Repeatability		Between-Run		Between-Day		Between-Instrument		Between-Site		Reproducibility	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
270	449.7	18.0	4.0	0.0	0.0	1.6	0.4	0.0	0.0	7.2	1.6	19.5	4.3
269[a]	450.6	9.2	2.0	3.6	0.8	0.0	0.0	1.3	0.3	8.2	1.8	12.9	2.9

[a] *A statistical outlier was identified via Grubb's test with a 0.05 significance level. Results after removal of the statistical outlier indicate improved poolability.*

Table 5: LQC precision results – ACT-LR directCHECK Level 1 (Normal)

N	Mean (sec.)	Repeatability		Between-Run		Between-Day		Between-Instrument		Between-Site		Reproducibility	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
270	146.2	16.7	11.4	1.0	0.7	0.0	0.0	4.4	3.0	1.5	1.0	17.4	11.9

Table 6: LQC precision results – ACT-LR directCHECK Level 2 (Abnormal)

N	Mean (sec.)	Repeatability		Between-Run		Between-Day		Between-Instrument		Between-Site		Reproducibility	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
270	309.3	26.3	8.5	0.0	0.0	1.6	0.5	5.5	1.8	0.0	0.0	26.9	8.7

Lot-to-Lot Precision Study

A precision study using two lots of each cartridge (cuvette) type was performed to assess the lot-to-lot variability. The study design involved one site, 20 days, two runs per day, two replicates per run, across two lots of each cartridge type (ACT+ and ACT-LR), with each lot run on four instruments by two operators. One lot of each directCHECK liquid quality control level (Level 1 and Level 2) was used. At each LQC level, estimates of within-run, between-run, between-day, between-instrument, between-operator, between-lot, and total (within-laboratory) precision were obtained. The results, which all met acceptance criteria, are summarized in the tables below. Overall, the study results demonstrated acceptable precision across different lots of assay cartridge.

Table 7: LQC precision results – ACT+ directCHECK Level 1 (Normal)

N	Mean	Within-Run		Between-Run		Between-Day		Between-Instrument		Between-Operator		Between Cartridge Lot		Total	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
640	157.7	11.4	7.2	1.7	1.1	2.7	1.7	3.1	2.0	1.0	0.6	0.0	0.0	12.3	7.8

Table 8: LQC precision results - ACT+ directCHECK Level 2 (Abnormal)

N	Mean	Within-Run		Between-Run		Between-Day		Between-Instrument		Between-Operator		Between Cartridge Lot		Total	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
640	419.0	9.7	2.3	2.5	0.6	1.9	0.5	3.5	0.8	0.0	0.0	1.8	0.4	10.9	2.6

Table 9: LQC precision results - ACT-LR directCHECK Level 1 (Normal)

N	Mean	Within-Run		Between-Run		Between-Day		Between-Instrument		Between-Operator		Between Cartridge Lot		Total	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
640	117.1	10.5	9.0	2.1	1.8	4.3	3.7	4.8	4.1	2.8	2.4	2.2	1.9	13.0	11.1

Table 10: LQC precision results - ACT-LR directCHECK Level 2 (Abnormal)

N	Mean	Within-Run		Between-Run		Between-Day		Between-Instrument		Between-Operator		Between Cartridge Lot		Total	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
640	272.3	19.1	7.0	0.0	0.0	2.6	1.0	1.1	0.4	0.0	0.0	15.3	5.6	24.6	9.0

Whole Blood Precision

For the whole blood precision study, sample stability concerns warranted utilization of 10 instruments, two operators (each running five GEM Hemochron 100 instruments) each performing two replicates of each sample (N=20). Five ACT levels were tested with ACT+ and four ACT levels were tested with ACT-LR. The ACT levels were targeted such that they spanned the target measurement range of each assay. Each donor whole blood sample was tested at only one heparin level (i.e., one target clotting time). Intravenous blood was obtained and heparinized to the desired clotting time. ACT+ has a linear range of between 1.0 and 6.0 units/mL of heparin, and therefore samples other than baseline which contained less than 1.0 units/mL of heparin were not tested. ACT-LR has a linear range of between 0 and 2.5 units/mL of heparin, and therefore only samples within this range were used. Estimates of whole blood precision within-instrument, between-instrument, between operator and within-laboratory were obtained and summary data for this study is provided in the tables below. Overall, whole blood precision of GEM Hemochron 100 ACT+ and ACT-LR cartridges met the acceptance criteria.

Table 11: Whole blood precision results – ACT+

Test Type	ACT Target	Donor ID	N	Mean (s)	Within Instrument		Between Instrument		Between Operator		Within Laboratory	
					SD	%CV	SD	%CV	SD	%CV	SD	%CV
ACT+	68-180s	2082	20	105.9	5.6	5.3	4.6	4.3	5.0	4.8	8.8	8.4
	181-360s	2220	20	235.6	22.3	9.5	0.0	0.0	0.0	0.0	22.3	9.5
	361-540s	2012	20	375.7	6.6	1.8	0.0	0.0	0.0	0.0	6.6	1.8
	541-720s	406	20	708.3	41.3	5.8	20.2	2.9	0.0	0.0	46.0	6.5
	≥721s[1]	2209	20	772.1	98.7	12.8	0.0	0.0	21.6	2.8	101	13.1
	≥721s[1]	2209	19[a]	760.1	69.3	9.1	0.0	0.0	47.5	6.3	84.0	11.1

[1] *There is no acceptance criteria for this target clotting range which is above the medical decision level*

[a] *A statistical outlier was identified via Grubb's Test with a 0.05 significance level. Although there are no acceptance criteria for precision applied to this ACT CES level, results after removal of the statistical outlier indicate improved poolability and a passing result. Results from both analyses, with and without the outlier, are presented.*

Table 12: Whole blood precision results – ACT-LR

Test Type	ACT Target	Donor ID	N	Mean	Within Instrument		Between Instrument		Between Operator		Within Laboratory	
					SD	%CV	SD	%CV	SD	%CV	SD	%CV
ACT-LR	65-145s	324	20	117.5	5.9	5.0	0.0	0.0	0.0	0.0	5.9	5.0
	146-226s	2047	20	209.8	10.9	5.2	0.0	0.0	0.0	0.0	10.9	5.2
	227-307s	2226	20	266.8	12.5	4.7	11.8	4.4	0.0	0.0	17.2	6.4
	≥308s	2181	20	351.2	21.6	6.1	0.0	0.0	4.3	1.2	22.0	6.3

2. Linearity:

A linearity study was conducted, per CLSI EP06-A, to validate the linear range claim. Three cartridge lots were evaluated with two donors for each cartridge lot, or a total of six donors were tested for ACT+ and ACT-LR assay, respectively. Each donor's blood sample responded to heparin independently and a conclusion was made based on six sets of linearity test data. Seven heparin concentration levels were tested for each donor with eight data points by use of eight GEM Hemochron 100 instruments (i.e., one run on each instrument). Correlation between readings from the GEM Hemochron 100 instrument and heparin levels was evaluated by use of both linear and polynomial regression to define best fitting. Overall, the ACT+ assay on the GEM Hemochron 100 instrument demonstrated linear correlation of activated clotting time reading to heparin concentrations from 1.0 to 6.0 units/mL, and the ACT-LR assay on the GEM Hemochron 100 instrument demonstrated linear correlation of activated clotting time reading to heparin concentrations from 0 to 2.5 units/mL.

3. Analytical Specificity/Interference:

Refer to 510(k) cleared device: K050016

4. Assay Reportable Range:

Table 17: Assay Reportable Range	
Assay	**Reportable Range**
ACT+	76–1003 s
ACT-LR	68–397 s

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Refer to previous 510(k) clearances for ACT+ (K941007) test cuvette, ACT-LR (K960749) test cuvette, and directCHECK whole blood controls (K120977).

6. Detection Limit:

Not applicable

7. Assay Cut-Off:

   Not applicable

8. Accuracy (Instrument):

   Not applicable

9. Carry-Over:

   Refer to 510(k) cleared device: K050016

B Comparison Studies:

1. Method Comparison with Predicate Device:

   a. Internal Method Comparison Study

   An internal method comparison study was conducted to evaluate the performance of the ACT+ and ACT-LR assays on the GEM Hemochron 100 (GH100) platform versus the Hemochron Signature Elite (SE) platform, and to determine whether the results are statistically equivalent across the measurement range. The study utilized fresh whole blood samples from healthy donors which were spiked with different concentrations of heparin to cover the measurement range.

   The study design involved samples from 40 individuals tested in duplicate for each assay type (ACT+ and ACT-LR) and six instrument pairs (of GEM H100 and Signature Elite). One lot of each ACT+ and ACT-LR cartridge type was used. For the ACT+ assays, samples were tested at baseline and spiked with UFH to final concentrations of 1.0, 2.0, 3.0, 4.0, 5.0, and 6.0 units/mL. The results were compared and the bias was determined at medical decision levels of 400s and 500s. For the ACT-LR assays, samples were tested at baseline and spiked with UFH to final concentrations of 0.5, 1.0, 1.5, 2.0 and 2.5 units/mL. The results were compared and the bias was determined at medical decision levels of 225s and 300s.

   Passing-Bablok regression was performed using the first replicate obtained from each assay. The results from the Passing-Bablok analysis for the first replicate are shown below for ACT+ and ACT-LR assays. Slopes and intercepts, along with 95% confidence intervals, were calculated from the respective regression fit. Correlation coefficients were also computed. Overall, the results demonstrated that, for the levels of UFH tested, the results of ACT+ and ACT-LR assays ran on the GEM Hemochron 100 were comparable to the results of ACT+ and ACT-LR assays ran on the Hemochron Signature Elite.

Table 18: ACT+ Assay Results – GEM Hemochron 100 vs Hemochron Signature Elite

Results of Passing-Bablok Regression				% Bias at	
N	**Intercept (95% CI)**	**Slope (95% CI)**	**r**	**400s**	**500s**
280	2.877 (-1.572, 7.361)	1.007 (0.980, 1.026)	0.979	1.4%	1.2%

Table 19: ACT-LR Assay Results – GEM Hemochron 100 vs Hemochron Signature Elite

Results of Passing-Bablok Regression				% Bias at	
N	**Intercept (95% CI)**	**Slope (95% CI)**	**r**	**225 s**	**300 s**
215	-6.00 (-15.39, 2.388)	1.000 (0.9612, 1.049)	0.947	-2.7%	-2.0%

b. External Method Comparison Study

In addition to the Internal Method Comparison study, an External Method Comparison study was conducted at seven clinical sites in the United States, which were chosen for their specific representation of different types of sites and conditions expected during commercial clinical use, with trained users representative of point-of-care (POC) professional operators.

The study compared the GEM Hemochron 100 System against the predicate device Hemochron Signature Elite using patient fresh whole blood samples destined for discard. ACT+ cartridges were used in the cardiovascular operating room on patients with cardiac disease undergoing various cardiac surgery procedures, as well as on patients necessitating cardiac ablation in the electrophysiology lab. ACT-LR cartridges were used in various settings on patients requiring extracorporeal life support (ECLS) due to underlying heart and/or lung disease, as well as on patients with cardiac disease undergoing cardiac catheterization. For each ACT subject sample tested, two GEM Hemochron 100 instruments and two Hemochron Signature Elite instruments were needed. Each sample was assayed on paired GEM Hemochron 100 and paired Hemochron Signature Elite instruments by at least three trained operators at each site representative of POC users at a minimum of three clinical sites per cartridge type (ACT+ or ACT-LR).

Analysis methodology included linear regressions using Passing-Bablok analysis with the intercept and slope (along with the 95% confidence interval associated with each estimate), Bland-Altman plots of differences, Pearson product-moment correlation coefficient (r), overall average bias and bias at predefined clinically important decision points. These values were calculated for first replicate, at ranges appropriate for the cuvette type. The bias (with 95% confidence intervals) between GEM Hemochron 100 results and the Hemochron Signature Elite predicate results was calculated from the regression fit at the reference intervals (medical decision levels from Table 20). The results from the analysis using the first replicate are shown below for ACT+ and ACT-LR assays.

Table 20: Measuring Ranges for ACT+ and ACT-LR	
Measuring Ranges	**Clotting Time**
ACT-LR: procedures that require UFH up to 2.5 units/mL blood	
LR-NR (Normal Range)	≤170 sec Pre Heparin and Post Heparin
LR-TR (Therapeutic Range)*	200–300 sec
LR-HR (High Range)	≥300 sec
ACT+: procedures that require UFH of 1-6 units/mL blood	

Table 20: Measuring Ranges for ACT+ and ACT-LR	
Measuring Ranges	**Clotting Time**
+NR (Normal Range)	≤170 sec Pre Heparin and Post Heparin
+TR (Therapeutic Range)**	420–600 sec
+HR (High Range)	≥651 sec

*200 is the lower bound and 300 is the upper bound of ACT-LR therapeutic range
**420 is the lower bound and 600 is the upper bound of ACT+ therapeutic range

The method comparison study results were evaluated for individual sites and combined (pooled). In both analyses, the results met the predetermined acceptance criteria. The results from the pooled analysis as well as the individual site are summarized in the tables below. Linear regression and bias analysis were performed using the first replicate measurement from each instrument.

Table 21: Pooled ACT+ Results

Comparison	Results of Passing-Bablok Regression				% Bias at (95% CI)		
	N	Slope (95% CI)	Intercept (95% CI)	r	+NR (170 s)	+TR (420 – 600 s)	+HR (651 s)
GEM H100 vs Signature Elite (ACT+)	1279	1.04 (1.03, 1.06)	-4.33 (-7.99, -1.80)	0.95	1.6 (0.6, 2.3)	LB 3.1 (2.1, 4.1) UB 3.4 (2.3, 4.6)	3.5 (2.4, 4.7)

Table 22: Pooled ACT-LR Results

Comparison	Results of Passing-Bablok Regression				% Bias at (95% CI)		
	N	Slope (95% CI)	Intercept (95% CI)	r	LR-NR (170 s)	LR-TR (200 s)	LR-HR (300 s)
GEM H100 vs Signature Elite (ACT-LR)	463	0.96 (0.93, 1.00)	-3.173 (-9, 2.86)	0.95	-5.4 (-6.3, -4.3)	-5.1 (-6.1, -3.9)	-4.6 (-6.4, -2.7)

Table 23: ACT+ Results – Individual Sites

Site	Results of Passing-Bablok Regression				% Bias at (95% CI)		
	N	Slope (95% CI)	Intercept (95% CI)	r	+NR (170 s)	+TR (420 – 600 s)	+HR (651 s)
1	204	1.08 (1.02, 1.13)	-7.18 (-16.79, 0.45)	0.94	3.5 (1.0, 5.2)	LB 6.0 (2.1, 9.2) UB 6.6 (2.1, 10.1)	6.7 (2.1, 10.3)
2	631	1.05 (1.03, 1.07)	-3.52 (-8.16, 0.07)	0.95	3.0 (1.6, 3.9)	LB 4.3 (2.8, 5.3) UB 4.5 (2.9, 5.8)	4.6 (2.9, 5.9)
3	65	0.98 (0.86, 1.09)	1.33 (-31.36, 43.40)	0.90	-1.0 (-10.9, 11.8)	LB -1.5 (-4.7, 0.9) UB -1.6 (-7.1, 3.1)	-1.6 (-7.7, 3.5)
4	288	1.01 (0.98, 1.05)	-1.71 (-8.68, 4.12)	0.96	0.3 (-1.4, 1.9)	LB 0.9 (-1.0, 2.9) UB 1.1 (-1.2, 3.4)	1.1 (-1.3, 3.5)
5	87	1.0 (0.98, 1.03)	4.0 (-5.65, 9.11)	0.98	2.4 (-1.0, 3.7)	LB 1.0 (-0.2, 2.3) UB	0.6 (-0.8, 2.5)

Table 23: ACT+ Results – Individual Sites							
Site	Results of Passing-Bablok Regression				% Bias at (95% CI)		
	N	Slope (95% CI)	Intercept (95% CI)	r	+NR (170 s)	+TR (420 – 600 s)	+HR (651 s)
						0.7 (-0.7, 2.4)	

Table 24: ACT-LR Results – Individual Sites							
Site	Results of Passing-Bablok Regression				% Bias at (95% CI)		
	N	Slope (95% CI)	Intercept (95% CI)	r	LR-NR (170 s)	LR-TR (200 s)	LR-HR (300 s)
6	123	0.95 (0.86, 1.03)	2.65 (-10.91, 16.36)	0.92	-3.4 (-5.4, -1.8)	-3.7 (-6.1, -1.6)	-4.1 (-8.4, -0.4)
3	92	0.94 (0.86, 1.02)	2.48 (-15.55, 18.85)	0.92	-4.9 (-8.8, -0.3)	-5.1 (-8.5, -1.4)	-5.5 (-9.2, -2.1)
5	83	0.98 (0.86, 1.06)	-6.41 (-19.49, 8.74)	0.95	-6.0 (-9.8, -3.3)	-5.5 (-9.7, -2.2)	-4.4 (-10.9, 0.2)

Overall, the method comparison results demonstrated that, in the hands of point-of-care users representative of the settings where the instrument would be used (e.g. cardiovascular operating rooms, cardiac catheterization laboratories, electrophysiology laboratories, and extracorporeal life support), the GEM Hemochron 100 instrument performs equivalently to the predicate Hemochron Signature Elite instrument across the measurement range of ACT+ and ACT-LR test cartridges.

2. Matrix Comparison:

   Refer to 510(k) cleared device: K050016

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable

2. Clinical Specificity:

   Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

A study was conducted, per CLSI EP28-A3c, to establish the reference intervals for ACT+ and ACT-LR assays (000GACT+ and 000GACT-LR cartridges) on the GEM Hemochron 100 platform. The intervals were established for both healthy normal donors and for non-heparinized patients. The study included 120 donors for each subclass (normal donors and non-heparinized patients) and for each assay type. A nonparametric 95% reference interval was established for each subclass and 90% confidence interval limits were computed for each reference limit.

Table 25: GEM Hemochron 100 ACT+ and ACT-LR Reference Intervals				
Assay	**Donor Type**	**N**	**Lower Limit (90% CI)**	**Upper Limit (90% CI)**
ACT+	Normal Donors	120	82 (79–85)	133.8 (120–173)
	Non-UFH patients	120	82 (76–87)	174.3 (145–217)
ACT-LR	Normal Donors	120	116 (113–120)	155 (153–166)
	Non-UFH patients	120	83.2 (79–99)	199.5 (176–226)

F Other Supportive Instrument Performance Characteristics Data:

Summary of Design Control Activities:

Device Change	Potential Risks Introduced by the Change	Results	Deviations
Color touchscreen user interface	Screen icons, keyboard, navigation, EQC entry and QC utility using CCM do not function correctly or at all	PASS	None
Internal image sensor to scan barcodes on cartridge labels	2D barcodes on cartridge labels cannot be read by scanner	PASS	None
External scanner for operator and patient ID and LQC barcodes	Barcodes for operator ID (OID) or patient ID (PID) numbers or LQC data cannot be read by scanner	PASS	None
Internal scanner for clot time tracking	Scanning to detect sample movement and timing of clot formation does not function	PASS	None
Ethernet and POCT1-A2 Wi-Fi network	Connectivity, network selection and instrument configuration do not function	PASS	None
Software encryption	Confidential information and data integrity may be vulnerable	PASS	None
Improvements to CCM functionality	New features do not function or match predicate CCM	PASS	None
User interface updates based on feedback from usability studies	Design of user interface in commercial product does not meet requirements of certain users	PASS	None

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.