December 29, 2021

Accriva Diagnostics, Inc.
Brian James
Sr. Manager, Regulatory Affairs
6260 Sequence Drive
San Diego, California 92121

Re: K202101

Trade/Device Name: 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
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: Class II
Product Code: JPA, JBP, GGN
Dated: July 28, 2020
Received: July 29, 2020

Dear Brian James:

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 (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 located 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.

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Min Wu, Ph.D.
Acting Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202101

Device Name
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 Controls, Level 1 and Level 2, directCHECK ACT-LR Whole Blood Controls, Level 1 and Level 2

Indications for Use *(Describe)*

GEM Hemochron 100 System:
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 UFH 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..

GEM Hemochron 100 Activated Clotting Time Plus Test (ACT+):
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 the point-of-care. For in vitro diagnostic use.
For Professional Use, Rx Only.

GEM Hemochron 100 Low Range Activated Clotting Time Test (ACT-LR):
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 the point-of-care. For in vitro diagnostic use.
For Professional Use, Rx Only.

directCHECK Whole Blood Controls:
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.

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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510(k) Summary

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92. This is a Traditional 510(k)

1. Sponsor/Application Information and Date [807.92(A)(1)]

Owner/Manufacturer Name and Address:	Accriva Diagnostics, Inc. 6260 Sequence Drive San Diego, CA 92121 FEI Number: 2250033 Establishment Registration Number: 3002721930
Submitter Name and Address:	Accriva Diagnostics, Inc. 6260 Sequence Drive San Diego, CA 92121 FEI Number: 2250033 Establishment Registration Number: 3002721930
Contact Person:	Brian James Sr. Manager, Regulatory Affairs Accriva Diagnostics, Inc. (858) 263-2350 bjames@ilww.com
Application Correspondent:	Brian James Sr. Manager, Regulatory Affairs Accriva Diagnostics, Inc. (858) 263-2350 bjames@ilww.com
Date Summary Prepared:	December 24th, 2021

2. Device Name and Classification [807.92 (A)(2)]

Trade Name	Common Name	Classification Name	Classification	Product Code
GEM® Hemochron™ 100 System	Coagulation Analyzer	Multipurpose system for in vitro coagulation studies	Class II 21 CFR 864.5425	JPA
GEM® Hemochron™ 100 Activated Clotting Time Plus Test (ACT+)	ACT Whole Blood Clotting Assay	Activated whole blood clotting time tests	Class II 21 CFR 864.7140	JBP
GEM® Hemochron™ 100 Low Range Activated Clotting Time Test (ACT-LR)	ACT Whole Blood Clotting Assay	Activated whole blood clotting time tests	Class II 21 CFR 864.7140	JBP
directCHECK™ ACT+ Whole Blood Controls, Level 1 and Level 2	Plasma Coagulation Control	Multipurpose system for in vitro coagulation studies	Class II (exempt) 21 CFR 864.5425	GGN
directCHECK™ ACT-LR Whole Blood Controls, Level 1 and Level 2	Plasma Coagulation Control	Multipurpose system for in vitro coagulation studies	Class II (exempt) 21 CFR 864.5425	GGN

3. Identification of Legally Marketed Predicate Device [807.92(A)(3)]

Trade Name	Predicate Device	Predicate 510(k) Number
GEM® Hemochron™ 100 System	Hemochron™ Signature Elite Microcoagulation System	K193041
GEM® Hemochron™ 100 Activated Clotting Time Plus Test (ACT+)	Hemochron™ Activated Clotting Time Plus (ACT+) Test	K941007
GEM® Hemochron™ 100 Low Range Activated Clotting Time Test (ACT-LR)	Hemochron™ Low Range Activated Clotting Time (ACT-LR) Test	K960749
directCHECK™ ACT+ Whole Blood Controls, Level 1 and Level 2	*direct*CHECK™ Control for Hemochron Jr. Microcoagulation Systems ACT+ and ACT-LR cuvettes	K120977
directCHECK™ ACT-LR Whole Blood Controls, Level 1 and Level 2	*direct*CHECK™ Control for Hemochron Jr. Microcoagulation Systems ACT+ and ACT-LR cuvettes	K120977

4. Device Description [807.92 (A)(4)]

Trade Name	Device Description
GEM® Hemochron™ 100 System	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. The analyzer 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. The analyzer contains a test chamber which warms a test cartridge 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 cartridge 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 expiry 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 GEM® Hemochron™ 100 system is intended for use at the point of care professional healthcare environments such as the Cardiovascular Operating Room and Catheterization lab and is designed to perform its essential tasks of performing in-vitro diagnostic blood coagulation-time tests without the use of a network connection. 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 (LIS/HIS) 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.

This instrument complies with the requirements of FCC Part 15 Subpart B, Innovation, Science and Economic Development Canada (ISED) ICES-003, and EN 61326-1:2013 as shown below:

FCC ID:	2AQV3-GEM100
IC Certificate:	24216-GEM100
Product Name:	GEM Hemochron 100
Model(s):	GEM100
Equipment Type:	Wireless Handheld Hemochron
Classification:	Portable Transmitter Handheld Only
TX Frequency Range:	2412–2462 MHz; 5180–5320 MHz; 5500–5700 MHz; 5745–5825 MHz
Frequency Tolerance:	±2.5 ppm
Maximum RF Output:	2450 MHz (b) –15.50 dB, 2450 MHz (g) – 19.00 dB, 2450 MHz (n) – 21.50 dB, 5250 MHz (a) – 16.00 dB, 5250 MHz (n) – 16.00 dB, 5600 MHz (a) – 17.50 dB, 5600 MHz (n) – 17.50 dB, 5800 MHz (a) – 17.00 dB, 5800 MHz (n) – 17.00 dB Conducted
Signal Modulation:	DSSS, OFDM
Antenna Type:	Internal; PIFA Antenna
FCC Rule Parts:	Part 2, 15C, 15E
KDB Test Methodology:	KDB 447498 D01 v06, KDB 248227 v02r02, KDB 616217 D04 v01r02
Industry Canada:	RSS-102 Issue 5, Safety Code 6
Maximum SAR Value:	1.02 W/kg Reported 10 Gram Average
Maximum Simultaneous SAR:	1.45 W/kg Reported 10 Gram Average
Separation Distance:	0 mm

The GEM Hemochron 100 utilizes the following list of wireless technologies:

Band	**Technology**	**3GPP Nominal Power dBm**	**Setpoint Nominal Power dBm**	**Tolerance dBm**	**Lower Tolerance dBm**	**Upper Tolerance dBm**
WLAN – 2.4 GHz	802.11b	N/A	13.5	±2	11.5	15.5
WLAN – 2.4 GHz	802.11g	N/A	17.0	±2	15.0	19.0
WLAN – 2.4 GHz	802.11n	N/A	19.5	±2	17.5	21.5
WLAN – 5 GHz Band I, IIA	802.11a (36–56)	N/A	13.0	±2	11.0	15.0

	<table><tr><td>WLAN – 5 GHz Band IIA</td><td>802.11a (60–64)</td><td>N/A</td><td>14.0</td><td>±2</td><td>12.0</td><td>16.0</td></tr><tr><td>WLAN – 5 GHz Band I, IIA</td><td>802.11n (36–56)</td><td>N/A</td><td>13.0</td><td>±2</td><td>11.0</td><td>15.0</td></tr><tr><td>WLAN – 5 GHz Band IIA</td><td>802.11n (60–64)</td><td>N/A</td><td>14.0</td><td>±2</td><td>12.0</td><td>16.0</td></tr><tr><td>WLAN – 5 GHz Band IIC</td><td>802.11a</td><td>N/A</td><td>15.5</td><td>±2</td><td>13.5</td><td>17.5</td></tr><tr><td>WLAN – 5 GHz Band IIC</td><td>802.11n</td><td>N/A</td><td>15.5</td><td>±2</td><td>13.5</td><td>17.5</td></tr><tr><td>WLAN – 5 GHz Band III</td><td>802.11a</td><td>N/A</td><td>15.0</td><td>±2</td><td>13.0</td><td>17.0</td></tr><tr><td>WLAN – 5 GHz Band III</td><td>802.11n</td><td>N/A</td><td>15.0</td><td>±2</td><td>13.0</td><td>17.0</td></tr></table>
GEM® Hemochron™ 100 Activated Clotting Time Plus Test (ACT+)	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 (000GACT+) are identical in composition to those in the predicate Hemochron™ ACT+ cuvettes (JACT-LR). 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. Each box of GEM® Hemochron™ 100 ACT+ cartridges contain 45 pouches, each pouch containing one GEM® Hemochron™ 100 ACT+ cartridge and one desiccant packet.
GEM® Hemochron™ 100 Low Range Activated Clotting Time	GEM® Hemochron™ 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

Test (ACT-LR)	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 (000GACT-LR) are identical in composition to those in the predicate Hemochron™ ACT-LR cuvettes (JACT-LR). 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. Each box of GEM® Hemochron™ 100 ACT-LR cartridges contain 45 pouches, each pouch containing one GEM® Hemochron™ 100 ACT-LR cartridge and one desiccant.
directCHECK™ Whole Blood Quality Controls, Level 1 and Level 2	Blood coagulation instruments and assays should be quality controlled prior to and during routine use. Performance ranges are provided with each control product against which users should compare results. Quality assurance programs include instrument service, quality control and complete performance records. directCHECK™ Quality Control products are to be used with Hemochron Systems (GEM® Hemochron™ 100 and Hemochron™ Signature Series). Level 1 and Level 2 QC products are provided in separate packaging. These preparations consist of dried fixed bovine red blood cells, rabbit cephalin, buffered sheep and horse plasma. Assayed clotting time values are provided with each lot of material. Each control preparation is provided in a dropper vial. Each dropper vial also contains diluent used to rehydrate the dried whole blood control. Diluent preparations consist of distilled water, sodium chloride, Tween® 20, ProClin®, and anticoagulant.

5. Intended Use [807.92(A)(5)]

Trade Name	Intended Use/Indications for Use
GEM® Hemochron™ 100 System	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 UFH 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.
GEM® Hemochron™ 100 Activated Clotting Time Plus Test (ACT+)	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 the point-of-care. For in vitro diagnostic use. For Professional Use, Rx Only.
GEM® Hemochron™ 100 Low Range Activated Clotting Time Test (ACT-LR)	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 the point-of-care. For in vitro diagnostic use. For Professional Use, Rx Only.
directCHECK™ Whole Blood Quality Controls, Level 1 and Level 2	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.

6. Technological Similarities and Differences to the Predicate [807.92 (A)(6)]

The following is a description of the similarities and differences between the predicate device; the currently marketed Hemochron™ Signature Elite (K193041), compared to the subject device, GEM® Hemochron™ 100 System, to demonstrate substantial equivalence.

6.1. GEM® Hemochron™ 100

Instrument Characteristics	Hemochron™ Signature Elite (Predicate Device – K193041)	GEM® Hemochron™ 100 System (Subject Device)
Similarities		
Intended Use	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.	✓ Substantially Equivalent 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 UFH 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.
Assays Used	Activated Clotting Time (ACT+ and ACT-LR) Activated Partial Thromboplastin Time (APTT and APTT Citrate) Prothrombin Time (PT and citrate-PT)	✓ Substantially Equivalent Activated Clotting Time (ACT+ and ACT-LR) only
Sample Type	Fresh Whole Blood Citrated Whole Blood	✓ Substantially Equivalent Fresh Whole Blood only
Reagents	Supplied in self-contained disposable cuvettes	✓ Substantially Equivalent Supplied in self-contained disposable cartridges (cuvettes)
Reported Results	Celite ACT Equivalent Time – ACT+ and ACT-LR PT, citrate-PT (INR) Whole Blood Values – APTT, citrate-APTT, PT, citrate-PT Plasma Equivalent (PE) Values – APTT, citrate-APTT, PT, citrate-PT	✓ Substantially Equivalent ACT Celite-equivalent value (CEV) in seconds – ACT+ and ACT-LR
Precision	≤10% C.V. for whole blood samples	✓ Substantially Equivalent
Results	Displayed on LCD screen	✓ Substantially Equivalent
Timing Range	0 seconds to 1005 seconds	✓ Substantially Equivalent
Operating Environment	15° to 30°C	✓ Substantially Equivalent 15° to 30°C
Clot Detection Method	Mechanical-optical clot detection	✓ Substantially Equivalent
Liquid QC Requirement	Two levels – performed as directed	✓ Substantially Equivalent
Electronic QC Requirement	Internal electronic QC	✓ Substantially Equivalent
Heater temperature control	Thermistor – modulated by software	✓ Substantially Equivalent
Power	Battery or AC operated	✓ Substantially Equivalent
Differences		
Operating System	IA188EBP	Android 7.1 (Nougat)
Software Version	2.4	1.1
Dimensions and weight	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)	Width 10.2 cm (4.0 inches) Length 19 cm (7.4 inches) Depth 5 cm (2.0 inches) Weight 0.68 kg (1.5 pounds)

PC Connectivity	RS-232 and Ethernet ports; POCT1-A2	Wi-Fi and Ethernet ports; POCT1-A2
Data Storage Capacity	16- alphanumeric character OID / 20-character PID; 600 QC and test records	32- alphanumeric character OID / 32-character PID; 10,000 QC and test records
Optical Detection System	LED	Internal camera
User Interface	Keypad and barcode scanner	Touch screen and barcode scanner
OID / PID Input	Keypad	Touch screen and barcode scanner
LQC Parameter Input	Keypad and barcode scanner	Touch screen and barcode scanner
Assay Parameter Input	Keypad and barcode scanner	Touch screen and external barcode scanner
Supported Barcode Formats	UPC/EAN, Code 128, Code 39, Trioptic Code 39, Code 93, Interleaved 2 of 5, Discrete 2 of 5, Codabar, and MSI Plessey	Aztec, Code 39, Code 128, Micro PDF417, PDF417, QR
Incubation Warm Up Time	Up to 200 seconds	30 to 90 seconds

6.2. GEM® Hemochron™ 100 ACT+

Assay Characteristics	**Hemochron™ ACT+ (Predicate Device – K941007)**	**GEM® Hemochron™ 100 ACT+ (Subject Device)**
	Similarities	
Intended Use	The Hemochron™ Jr. ACT+ is a quantitative assay for monitoring heparin anticoagulation during various medical procedures. The ACT+ demonstrates linear correlation to the anticoagulation effects of heparin between 1.0 and 6.0 units/ml of blood. It is intended for use in monitoring moderate to high heparin doses frequently associated with cardiac catheterization and cardiopulmonary bypass surgery. The test is unaffected by aprotinin. The ACT+ is not sensitive to very low levels of heparin such as those encountered in critical care. The Hemochron Jr. APTT and ACT-LR are available for monitoring low levels of heparin. The ACT+ test is performed on any Hemochron Jr. model using a fresh whole blood sample. Each instrument is portable and intended for bedside use. The instrument is not intended for home use. For in vitro Diagnostic Use, For Professional Use, Rx Only.	✓ Substantially Equivalent 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 the point-of-care. For in vitro diagnostic use. For Professional Use, Rx Only.

Reagents	Silica, Kaolin, Phospholipid, Stabilizers and Buffers	✓ Substantially Equivalent Silica, Kaolin, Phospholipid, Stabilizers and Buffers
Normal Range	81-125 Celite Equivalent Seconds	✓ Substantially Equivalent 82-133.8 Celite Equivalent Seconds
Heparin Linearity	1.0-6.0 heparin units/mL of blood	✓ Substantially Equivalent 1.0-6.0 heparin units/mL of blood
Sample Type	Fresh Whole Blood	✓ Substantially Equivalent Fresh Whole Blood
Controls	directCHECK™ Whole Blood Controls	✓ Substantially Equivalent directCHECK™ Whole Blood Controls
Packaging	45 pouched single-use test cuvettes	✓ Substantially Equivalent 45 pouched single-use test cartridges (cuvettes)
Storage Temperature	2-8°C	✓ Substantially Equivalent 2-8°C
Differences		
Label	Hole Code read by instrument	2D Barcode read by instrument
Catalog Number	JACT+	000GACT+

NOTE: *000GACT+ is identical to JACT+, in every aspect except for the noted distinctions (e.g. name and 2D barcode).*

6.3. GEM® Hemochron™ 100 ACT-LR

Assay Characteristics	**Hemochron™ ACT-LR (Predicate Device – K960749)**	**GEM® Hemochron™ 100 ACT-LR (Subject Device)**
Similarities		
Intended Use	The Hemochron™ Jr. ACT–LR is a quantitative assay for monitoring heparin anticoagulation during various medical procedures. The ACT–LR demonstrates linear correlation to the anticoagulation effects of heparin up to 2.5 units/ml of blood. It is intended for use in monitoring low to moderate heparin doses frequently associated with procedures such as cardiac cath-eterization, Extracorporeal Membrane Oxygenation (ECMO), hemodialysis, and Percutaneous Transluminal Coronary Angioplasty. (The Hemochron Jr. ACT+ [JACT+] test is available for monitoring moderate to high levels [1-6 units/ml] of heparin.) The ACT–LR test is performed on any Hemochron Jr. model using a fresh whole blood sample. Each instrument is portable and is intended for bedside use. The instrument is not intended for home use.	✓ Substantially Equivalent 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 the point-of-care.

	For in vitro Diagnostic Use, For Professional Use, Rx Only.	For in vitro diagnostic use. For Professional Use, Rx Only.
Reagents	Celite and Silicon Dioxide Activators, Potato Dextrin, Stabilizers and Buffers	✓ Substantially Equivalent Celite and Silicon Dioxide Activators, Potato Dextrin, Stabilizers and Buffers
Normal Range	113-149 Celite Equivalent Seconds	✓ Substantially Equivalent 116-155 Celite Equivalent Seconds
Heparin Linearity	Up to 2.5 heparin units/mL of blood	✓ Substantially Equivalent Up to 2.5 heparin units/mL of blood
Sample Type	Fresh Whole Blood	✓ Substantially Equivalent Fresh Whole Blood
Controls	directCHECK™ Whole Blood Quality Controls	✓ Substantially Equivalent directCHECK™ Whole Blood Quality Controls
Packaging	45 pouches, each containing 1 sing-use test cuvette	✓ Substantially Equivalent 45 pouches, each containing 1 sing-use test cartridge (cuvette)
Storage Temperature	2-8°C	✓ Substantially Equivalent 2-8°C
Differences		
Label	Hole Code read by instrument	2D Barcode read by instrument
Catalog Number	JACT-LR	000GACT-LR

NOTE: *000GACT-LR is identical to JACT-LR, in every aspect except for the noted distinctions (e.g. name and 2D barcode).*

6.4. directCHECK™ Whole Blood Quality Controls

Control Characteristics	**directCHECK™ Whole Blood Controls** **ACT+ and ACT-LR** **(Predicate Device – K120977)**	**directCHECK™ Whole Blood Quality Controls** **(Subject Device)**
Similarities		
Intended Use	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 Microcoagulation test cuvettes. For in vitro Diagnostic Use. For Professional Use, Rx Only.	✓ Substantially Equivalent 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.
Preparation	Distilled Water, Sodium Chloride, Tween® 20, ProClin® and anticoagulant	✓ Substantially Equivalent Distilled Water, Sodium Chloride, Tween® 20, ProClin® and anticoagulant
Packaging	15 single use vials	✓ Substantially Equivalent 15 single use vials
Storage Temperature	2-8°C	✓ Substantially Equivalent 2-8°C

Differences		
Catalog Number	DCJACT-N DCJACT-A DCJLR-N DCJLR-A	000DCGACT-1 000DCGACT-2 000DCGLR-1 000DCGLR-2

NOTE: *000DCGACT-1, 000DCGACT-2, 000DCGLR-1, 000DCGLR-2 are identical to DCJACT-N, DCJACT-A, DCJLR-N, DCJLR-A in every aspect except for the noted distinctions (e.g. name).*

7. Summary of Non-Clinical Performance Data

7.1. GEM Hemochron 100 System

The GEM Hemochron 100 System was successfully tested for electrical safety, emissions and immunity, and wireless performance to the following standards:

Description	Standard	Title
Electrical Safety	IEC 61010-1	Safety requirements for electrical equipment for measurement, control and laboratory use. Part 1: General requirements
	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	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

	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
	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

7.2. Precision - Liquid Quality Controls (Celite Equivalent Seconds):

LQC samples were tested in accordance with CLSI EP05-A3 with a test design of 1 site, 20 days (non-sequential), 2 runs per day, and 2 replicates per run, across 2 GEM® Hemochron™ 100 ACT+ and ACT-LR cartridge lots using the GEM® Hemochron™ 100 System

7.2.1. GEM® Hemochron™ 100 ACT+

			Within-run	
	N	**Mean(s)**	**SD**	**%CV**
Level 1	640	157.7	11.4	7.2%
Level 2	640	419.0	9.7	2.3%

7.2.2.GEM® Hemochron™ 100 ACT-LR

			Within-run	
	N	**Mean(s)**	**SD**	**%CV**
Level 1	640	117.1	10.5	9.0%
Level 2	640	272.3	19.1	7.0%

7.3. Precision – Donor whole blood samples (Celite Equivalent Seconds)

The study design included a total of 20 test replicates per donor sample (e.g. 2 operators x 5 instruments per operator x 2 test results per instrument).

7.3.1.GEM® Hemochron™ 100 ACT+

			Within-instrument	
Sample Target Ranges	**N**	**Mean(s)**	**SD**	**%CV**
68-180	20	105.9	5.6	5.3%
181-360	20	235.6	22.3	9.5%
361-540	20	375.7	6.6	1.8%
541-720	20	708.3	41.3	5.8%
>=721	19	760.1	69.3	9.1%

7.3.2.GEM® Hemochron™ 100 ACT-LR

			Within-instrument	
Sample Target Ranges	**N**	**Mean(s)**	**SD**	**%CV**
65-145	20	117.5	5.9	5.0%
146-226	20	209.8	10.9	5.2%
227-307	20	266.8	12.5	4.7%
>=308	20	351.2	21.6	6.1%

7.4. Method Comparison Study

7.4.1.GEM® Hemochron™ 100 ACT+

A method comparison study was performed in accordance with CLSI EP09-A3, using whole blood samples from 40 normal subjects, comparing the GEM® Hemochron™ 100 and Hemochron™ Signature Elite. Samples were assayed 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.

Comparison	**Results of Passing-Bablok Regression**				**% Bias at**	
	n	**Intercept (95% C.I.)**	**Slope (95% C.I.)**	**r**	**400 s**	**500 s**
GEM® Hemochron™ 100 vs Hemochron™ Signature Elite	280	2.877 (-1.572, 7.361)	1.007 (0.988, 1.026)	0.979	1.4%	1.2%

7.4.2. GEM® Hemochron™ 100 ACT-LR

An in-house method comparison study was performed in accordance with CLSI EP09-A3 using whole blood samples from 40 normal subjects, comparing GEM® Hemochron™ 100 and Hemochron™ Signature Elite. Samples were assayed at baseline and spiked with UFH to final concentrations of 0.5, 1.0, 1.5, and 2.5 units/mL. The results were compared and the bias was determined at medical decision levels of 225s and 300s.

Comparison	Results of Passing-Bablok Regression				% Bias at	
	n	Intercept (95% C.I.)	Slope (95% C.I.)	r	225 s	300 s
GEM® Hemochron™ 100 vs Hemochron™ Signature Elite	215	-6.00 (-15.39, 2.388)	1.0000 (0.9612, 1.049)	0.947	-2.7%	-2.0%

8. Conclusion:

Based on the substantial equivalence comparison and the results of the conducted performance evaluations, it was concluded that the performance of the GEM® Hemochron™ 100 to be substantially equivalent to the cleared and currently marketed predicate device, Hemochron™ Signature Elite (K193041). The differences between the subject and predicate do not impact safety and effectiveness.