November 22, 2019

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

Re: K193041
Trade/Device Name: Hemochron Signature Elite
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose System For In Vitro Coagulation Studies
Regulatory Class: Class II
Product Code: JPA
Dated: October 30, 2019
Received: October 31, 2019

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,

Takeesha Taylor-Bell
Acting Deputy Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Hemochron™ Signature Elite

Indications for Use *(Describe)*
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.

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

Submitter's Information	Accriva Diagnostics, Inc. 6260 Sequence Drive San Diego, CA 92121, USA

Contact Person	Brian James, Senior Manager, Regulatory Affairs Phone: 858-263-2350 Email: bjames@ilww.com

Preparation Date	October 30, 2019

Device Trade Name	Hemochron™ Signature Elite

Regulatory Information	Classification: Class II Regulation No.: 21 CFR 864.5425 Common Name: System, Multipurpose For In Vitro Coagulation Studies Panel: Hematology (81) Product Code: JPA

Predicate Device	Hemochron™ Signature Elite: K050016

Indications for Use / 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.

Device Description	The Hemochron™ Signature Elite Whole Blood Microcoagulation System is a battery operated hand-held instrument. The system is intended for use in clinical settings requiring point of care testing. Whole blood test results are displayed as clotting times (in seconds). The instrument also displays correlated Celite® equivalent ACT values, APTT and PT plasma equivalent values, and the PT INR value. The Hemochron™ Signature Elite Whole Blood Microcoagulation System 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 front panel contains a keypad with various action keys as well as a number pad. The operator uses the keypad to select a command or enter information. The instrument also includes a barcode scanner for reading of barcode identifications (IDs). Data management capabilities are included with the instrument. These capabilities include storage of up to 600 patient results and 600 quality control results, designation of quality control levels, tagging of test results with date and time, entry of Patient ID and/or Operator ID or Operator PIN, and printing of results.

Description of Modification	This Special 510(k) is being submitted to update the Hemochron™ Signature Elite software from Version 2.3 to Version 2.4.

Reason Submission Qualifies as Special 510(k)	The submission meets the criteria for a Special 510(k) based on the following: • The proposed change is submitted by the manufacturer legally authorized to market the existing device • Performance data are unnecessary, or if performance data are necessary, well-established methods are available to evaluate the change; and • All performance data necessary to support Substantial Equivalence (SE) can be reviewed in a summary or risk analysis format. In addition, the changes described in this submission do not introduce: • Changes to indications for use or intended use • Changes to operating principle • Changes to analytical performance claims • Changes to assay algorithms

Comparison to Predicate Device (K050016):

The following is a description of the similarities and differences between the predicate device; the currently marketed Hemochron™ Signature Elite (K050016), compared to the subject device, Hemochron™ Signature Elite with updated software Version 2.4, to demonstrate substantial equivalence.

Instrument Characteristics	**Hemochron™ Signature Elite** **(Predicate Device - K050016)**	**Hemochron™ Signature Elite** **(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 HemochronTM 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) **Activated Partial Thromboplastin Time** (APTT and APTT Citrate) **Prothrombin Time** (PT and PT Citrate)	✓ Substantially Equivalent **Activated Clotting Time** (ACT+ and ACT-LR) **Activated Partial Thromboplastin Time** (APTT and APTT Citrate) **Prothrombin Time** (PT and PT Citrate)
Sample Type	Fresh Whole Blood	✓ Substantially Equivalent

	Citrated Whole Blood	Fresh Whole Blood Citrated Whole Blood
Reagents	Supplied in self-contained disposable cuvette	✓ Substantially Equivalent Supplied in self-contained disposable cuvette
Reported Results	Celite ACT Equivalent Time – ACT+, ACT-LR International Normalized Ratios (INR) – PT, citrate-PT Whole Blood values - APTT, citrate-APTT, PT, citrate-PT Plasma Equivalent (PE) Values – APTT, citrate-APTT, PT, citrate-PT	✓ Substantially Equivalent Celite ACT Equivalent Time – ACT+, ACT-LR International Normalized Ratios (INR) – PT, citrate-PT Whole Blood values - APTT, citrate-APTT, PT, citrate-PT Plasma Equivalent (PE) Values – APTT, citrate-APTT, PT, citrate-PT
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°C - 30 °C	✓ Substantially Equivalent 15°C - 30 °C
Clot detection method	Mechanical-optical clot detection	✓ Substantially Equivalent
Liquid QC Requirement	Two levels – Performed as directed	✓ Substantially Equivalent
Power	Battery or AC operated	✓ Substantially Equivalent
PC Connectivity	RS-232 and Ethernet Ports	✓ Substantially Equivalent
User/Patient Data Input	User keypad or barcode scanner entry	✓ Substantially Equivalent
Data Storage Capacity	16 OID/20 PID alphanumeric characters 600 entries	✓ Substantially Equivalent
Electronic QC Requirement	Internal electronic QC	✓ Substantially Equivalent

Assay Parameter Input	User keypad or barcode scanner entry	✓ Substantially Equivalent
LQC Parameter Input	User keypad or barcode scanner entry	✓ Substantially Equivalent
Differences		
Incubation Warm Up Time	30 seconds to 90 seconds	Up to 200 seconds
Software Version	V2.3	V2.4

Conclusion:

Based on the identical indications for use, operating principle, analytical performance claims, and assay algorithms, the Hemochron™ Signature Elite with software Version 2.4 can be concluded to be substantially equivalent to the cleared and currently marketed predicate device, Hemochron™ Signature Elite (K050016).