510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:

K050016

B. Purpose for Submission:

Software update and instrument name change

C. Manufacturer and Instrument Name:

International Technidyne Corporation (ITC), HEMOCHON® Signature *Elite*™ Whole Blood Microcoagulation System

D. Type of Test or Tests Performed:

Quantitative coagulation tests (ACT, APTT, PT) using mechanical-optical clot detection

E. System Descriptions:

1. 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.

HEMOCHRON® *Configuration Manager* Software is included with the instrument. This software allows the user to connect a personal computer to the instrument and perform system configuration functions using a Microsoft® Windows® user interface. HEMOCHRON® *Report Maker*™ and *idms*™ software which are provided separately allows the user to connect a personal computer to the instrument and perform various data management and data reporting functions.

The HEMOCHRON® Signature *Elite*™ Whole Blood Microcoagulation System performs the same assays as the predicate instrument HEMOCHRON® Jr. Signature +™ Whole Blood Microcoagulation System (K020798) and uses the same clot detection system/method and clot detection algorithms. The submitted design upgrades the user interface, data storage and data manipulation functions. The instrument provides a secondary information input pathway using a barcode scanner in addition to manual keypad entry and offers a larger capacity to store data. The modifications described above for the HEMOCHRON® Signature *Elite*™ Whole Blood Microcoagulation System do not alter the intended use, the indications for use, nor the fundamental scientific technology.

The HEMOCHRON® *Configuration Manager* Software which was cleared with the HEMOCHRON® Jr. Signature +™ Whole Blood Microcoagulation System (K020798) has the same functionality.

2. Principles of Operation:

   The HEMOCHRON® Signature *Elite*™ Whole Blood Microcoagulation System employs a combination mechanical-optical clot detection mechanism. Blood is placed in a collection reservoir of a test cuvette and subsequently drawn into the test channel of the cuvette, which contains the reagent required to perform the respective coagulation assay. As blood is actively pumped back and forth in the test channel, LED detectors measure the position of the blood. As clotting begins to occur, the movement of the blood decreases below a pre-determined rate where the endpoint is recorded.

   The HEMOCHRON® Signature *Elite*™ Whole Blood Microcoagulation System employs the same clot detection mechanism as the predicate HEMOCHRON® Jr. Signature +™ (K020798).

3. Modes of Operation:

   The mode of operation of the HEMOCHRON® Signature *Elite*™ Whole Blood Microcoagulation System is random access. Tests are performed with single-use disposable test cuvettes. The instrument alerts the operator to place a drop of blood in the sample well of the cuvette and begin the test by pressing the start key.

4. Specimen Identification:

   Samples processed on the HEMOCHRON® Signature *Elite*™ Whole Blood Microcoagulation System are designated as patient samples by default. A patient ID can be entered for each test. The patient ID can be read from a barcode label using the internal barcode scanner or can be entered using the keypad.

5. Specimen Sampling and Handling:

   The HEMOCHRON® Signature *Elite*™ Whole Blood Microcoagulation System is intended to be used with test cuvettes that are available from ITC. A drop of blood is placed in the collection reservoir of a test cuvette and subsequently drawn in the test channel. Fresh or citrated whole blood samples collected directly from the patient are used. Reference is made to the package insert accompanying the HEMOCHRON Jr. test cuvettes for storage and handling.

6. Calibration:

   Not applicable.

7. Quality Control:

   The HEMOCHRON® Signature *Elite*™ Whole Blood Microcoagulation System should be tested at two levels every eight hours of operation. Automatic Internal Electronic Quality (EQC) can be used to provide a two level electronic verification of instrument performance, or liquid control products can be used. The EQC function is accessed through the QC Status menu by pressing the QC key before or after inserting a cuvette. The results are displayed while the test is in process. The EQC will check two levels of QC and the temperature, and will store the results. If one result fails, the test will stop and all record all results as failed.

   Cuvette validation is carried out using the appropriate HEMOCHRON Jr. Liquid Quality Control (LQC) product using the test procedure provided with the control.

8. Software:

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

   Yes___X_____ or No_____

   HEMOCHRON® *Configuration Manager* Software is included with the instrument. This software allows the user to connect a personal computer to the instrument and perform system configuration functions using a Microsoft® Windows® user interface. HEMOCHRON® *Report Maker*™ and *idms*™ software which are provided separately allows the user to connect a personal

computer to the instrument and perform various data management and data reporting functions.

The Risk Analysis of the HEMOCHRON® Signature *Elite*™ system identified the same risks as those for the predicate device as well as some additional risk based on the HEMOCHRON® Signature *Elite*™ system modifications. A Master Test Plan for validation and verification was provided along with a verification and validation certification to insure that the activities of the plan will be completed prior to the introduction of the product into interstate commerce in the United States.

F. Regulatory Information:

1. Regulation section:

   21 CFR 864.5425, Multipurpose system for In-Vitro Coagulation Studies

2. Classification:

   Class II

3 Product code:

   JPA, System, Multipurpose for In-vitro Coagulation Studies

4. Panel:

   Hematology (81)

G. 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 ITC.

1. Indication for 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. 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 HEMOCHRON® Signature *Elite*™ also displays correlated Celite® equivalent ACT values, APTT and PT plasma equivalent values, and the PT INR value.

2. Special Conditions for Use Statement(s):

   Not applicable.

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

   HEMOCHRON® Jr. Signature +™ Whole Blood Microcoagulation System, K020798

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
	HEMOCHRON® Signature *Elite*™	**HEMOCHRON® Jr. Signature +™**
Assays used	Activated Clotting Time (ACT+ and ACT-LR) Activated Partial Thromboplastin Time (APTT AND APTT Citrate) Prothrombin Time (PT and PT Citrate)	Same
Reagents	Supplied in self-contained disposable cuvette	Same
Results	Displayed on LCD screen	Same
Clot detection method	Mechanical-optical clot detection	Same
Liquid QC	Two levels-performed as directed	Same
Power	Battery or AC operated	Same

Differences		
Item	Device	Predicate
PC Connectivity	RS-232 and External Ports	RS-232 Port
User/Patient Data Input	User keypad or barcode scanner entry	User keypad entry
Data Storage Capacity	16 OID/20 PID alphanumeric characters 600 entries	9 OID/PID numeric characters 100 entries
Electronic QC Requirements	Internal or external electronic QC	External electronic QC cuvette

Differences		
Item	Device	Predicate
Temperature QC Requirements	Internally performed, verified and stored. User optional ability to externally verify using Temperature Verification Cuvette	Internally performed with ability to externally verify using Temperature Verification Cuvette
Assay Parameter Input	User keypad or barcode scanner entry	Not available
LQC Parameter Input	User keypad or barcode scanner entry	Not available

I. Special Control/Guidance Document Referenced (if applicable):

ISO 14971, "Medical Devices – Application of Risk Management to Medical Devices"
ISO 9001:1994 and ISO/DIS 13485 section 4.4.7 Design verification.
IEC 60825-1 (Safety of laser products – Part 1: Equipment classification requirements and user guide)

J. Performance Characteristics*:*

1. Analytical Performance:

a. Accuracy:

See data provided in previously 510(k) cleared **K020798**, HEMOCHRON® Jr. Signature +™ Whole Blood Microcoagulation System

b. Precision/Reproducibility:

See data provided in previously 510(k) cleared **K020798**, HEMOCHRON® Jr. Signature +™ Whole Blood Microcoagulation System

c. Linearity:

See data provided in previously 510(k) cleared **K020798**, HEMOCHRON® Jr. Signature +™ Whole Blood Microcoagulation System

d. Carryover:

See data provided in previously 510(k) cleared **K020798**, HEMOCHRON® Jr. Signature +™ Whole Blood Microcoagulation System

e. Interfering Substances:

See data provided in previously 510(k) cleared **K020798**, HEMOCHRON® Jr. Signature +™ Whole Blood Microcoagulation System

2. Other Supportive Instrument Performance Data Not Covered Above:

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

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