INTERNATIONAL
ITC
TECHNIDYNE
CORPORATION
8 Olsen Avenue ▾ Edison, NJ 08820
Toll Free Phone: (800) 631-5945
Phone: (732) 548-5700 FAX: (732) 632-9299

MAR 2 8 2002

510 (k) Summary

Hemochron® Jr. *Signature +*

This summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K020798

Prepared: March 6, 2002

Submitted by:
John Clay
International Technidyne Corp.
6 Olsen Ave.
Edison, NJ 08820
(732-548-5700) Ext. 265 (732-548-2325) Fax

Device Name

Common / Usual Name: Whole Blood Microcoagulation Test System

Product Name: HEMOCHRON® Jr. *Signature +*

Predicate Device

The Signature+ is substantially equivalent to the previously cleared Hemochron Jr. Signature instrument **K974799**.

Device Description and Technological Characteristics

The Hemochron Jr. Signature + instrument is an upgrade to the current Hemochron Jr. Signature instrument cleared under K974799 (July 1998).

The HEMOCHRON® *Signature+* is a portable, battery-operated point of care microcoagulation instrument designed to perform whole blood coagulation tests using fresh or citrated whole blood. The system is intended for use in many clinical settings requiring point-of-care testing.

The Signature Plus instrument performs the same assays as the predicate instrument. There are no modifications to the clot detection algorithm. The tests performed are the following:

Test Assay	**Application**	**Display Result Units**	**Equivalent Units Converted***
ACT-LR	Low Dose Heparin	Clotting Time Seconds	Hemochron Celite ACT
ACT+	High Dose Heparin	Clotting Time Seconds	Hemochron Celite ACT
APTT (fresh or citrated blood)	Low Dose Heparin Coagulation Screening	Clotting Time Seconds	Plasma APTT
PT (fresh or citrated blood)	Warfarin Monitoriing Coagulation Screening	Clotting Time Seconds INR	Plasma PT

* Converted equivalent units represent standard clinical terms.

The Signature Plus instrument employs the same clot detection mechanism as the predicate Signature. The clot detection mechanism is a combination mechanical-optical system. 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+* provides data management capabilities including the following:

- Patient and quality control result storage
- Input of operator and patient identification
- Designation of quality control level
- Date and time stamp for all test results
- Printer access
- Tests performed are tracked by test type and quality control failures

The HEMOCHRON® *Signature+* Configuration Manager (HCM) is a Windows-based software application. With this software, the Point-of-Care Coordinator (POCC) or Supervisor, may configure the HEMOCHRON® *Signature+* to meet the needs of the clinical setting. The functionality addressed with the Configuration Manager allows the POCC to set mandatory requirements for the input of operator and patient identifications, set limitations for liquid and electronic quality control, can prohibit operators from erasing database information or changing time/date settings. The POCC may also use the HCM to load predetermined notes (up to nine notes) into the Signature+ instrument that may be appended to the patient or quality control test. The HCM may be used to synchronize several HEMOCHRON® *Signature+* instruments to the same requirements via the PC connection.

New Features of the Hemochron Jr. Signature + Instrument

The modifications to the Hemochron Jr. Signature+ system include a software revision to the instrument, which allows for enhanced programming capability and flexibility for the user through the use of the Hemochron Configuration Manager (HCM Application Software), which is provided to the user for use in a Personal Computer (PC). These features have been described in the predicate device submission **(K974799).**

As described in that previous 510K, the interface between the Hemochron Jr. Signature and the PC required the use of a special cuvette, called the Commander Cuvette. The new Signature + software enables the activation of the PC interface software without using the Commander Cuvette. Accessing the PC interface is accomplished through the use of special hot keys on the instrument, which enables the user to interact with the instrument database and the HCM. The Signature + software modifications allow the user many additional programmable features.

The user interface for the clinician remains consistent with the previously cleared system with the exception of the enhanced features described in the revised operators manual including the features associated with the (HCM).

Statement of Intended Use

The HEMOCHRON® *Signature+* is a portable, battery-operated point of care microcoagulation instrument designed to perform whole blood coagulation tests using fresh or citrated whole blood. The system is intended for use in many clinical settings requiring point-of-care testing. Whole blood test results are displayed as clotting times (in seconds). The *Signature+* also displays correlated Celite® equivalent ACT values, APTT and PT plasma equivalent values, and the PT INR value.

For In Vitro Diagnostic Use Only

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 8 2002

Mr. John Clay
Director, Regulatory Affairs
International Technidyne Corporation
8 Olsen Avenue
Edison, New Jersey 08820

Re: k020798
Trade/Device Name: HEMOCHRON® Jr. *Signature* +
Regulation Number: 21 CFR § 864.5425
Regulation Name: Multipurpose System for In Vitro Coagulation Instruments
Regulatory Class: II
Product Code: JPA
Dated: March 11, 2002
Received: March 12, 2002

Dear Mr. Clay:

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. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (If Known): K020798

Device Name: HEMOCHRON® Jr. *Signature* +
Indications for Use:

The HEMOCHRON® *Signature*+ is a portable, battery-operated point of care microcoagulation instrument designed to perform whole blood coagulation tests using fresh or citrated whole blood. The system is intended for use in many clinical settings requiring point-of-care testing. Whole blood test results are displayed as clotting times (in seconds). The *Signature*+ also displays correlated celite equivalent ACT values, APTT and PT plasma equivalent values, and the PT INR value.

For In Vitro Diagnostic Use Only

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020798

Prescription Use ✓ or Over- the- Counter Use_____
Per 21 CFR 801.109

(Optional Format 1-2-96)