FEB 1 0 2005

510(k) Summary

K050016

Submitter Information

International Technidyne Corporation
8 Olsen Avenue
Edison, NJ 08820
(800) 631-5945

Establishment Registration Number: 2248721

Contact: Leslie Young
Date Prepared: 1/3/05

Device Information

Proprietary Name:	HEMOCHRON® *Signature Elite*™ Whole Blood Microcoagulation System
Common Name:	Microcoagulation Analyzer
Classification Name:	Multipurpose system for In-Vitro Coagulation (21 CFR 864.5425)
Device Class:	II
Panel:	Hematology & Pathology
Product Code:	81JPA

Predicate Device

Substantial equivalence is claimed to the currently marketed International Technidyne Corporation's HEMOCHRON® Jr. *Signature+* Whole Blood Microcoagulation System (K 020798).

Description of Device

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.

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® *ReportMaker*™ and *idms*™ software which are provided separately, allow the user to connect a personal computer to the instrument and perform various data management and data reporting functions.

For *in vitro* Diagnostic 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 ITC.

For *in vitro* Diagnostic Use.

Technological Comparison to Predicate
The HEMOCHRON® *Signature Elite*™ performs the same assays as the predicate instrument. It also uses the same clot detection system / method and clot detection algorithms as the predicate device. The submitted instrument 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.

HEMOCHRON® Configuration Manager, which was cleared in the same 510(k) as the predicate device, is a Microsoft® Windows® based software application. This software allows the user to configure the instrument to meet specific user needs in the clinical setting. The functionality of HEMOCHRON® Configuration Manager is the same for the HEMOCHRON® *Signature Elite*™ as the predicate device.

Substantial Equivalence Data Summary
Laboratory Comparison to Predicate
The HEMOCHRON® *Signature Elite*™ and predicate HEMOCHRON® Jr. *Signature*+ instruments were compared in the laboratory using ITC whole blood control products for each currently cleared 510(k) assay for the HEMOCHRON® Jr. *Signature*+ instrument (predicate).

Clinical Comparison to Predicate
A hospital evaluation was performed for the HEMOCHRON® *Signature Elite*™ clinical comparison to the predicate HEMOCHRON® Jr. *Signature*+ instrument system. The evaluation compared results obtained using split patient blood samples on the two instrument systems using each currently 510(k) cleared assay for the HEMOCHRON® Jr. *Signature*+ instrument system.

Clinical User Interface Evaluation
A user-based evaluation of the clinical utility and ease of use of the instructional format displayed on the HEMOCHRON® *Signature Elite*™ instrument system when compared to the predicate HEMOCHRON® Jr. *Signature*+ instrument system was performed.

All clinical and laboratory data demonstrate the substantial equivalence of the* HEMOCHRON® *Signature Elite*™ *instrument system to the predicate* HEMOCHRON® Jr. *Signature+ instrument system.

Substantial Equivalence Conclusion Summary

The modifications described herein for the HEMOCHRON® *Signature Elite*™ Whole Blood Microcoagulation System do not alter the intended use, the indications for use, nor the fundamental scientific technology used in the previously cleared predicate device. The HEMOCHRON® *Signature Elite*™ is substantially equivalent to the previously cleared HEMOCHRON® *Signature+*™ Whole Blood Microcoagulation System (K020798).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 10 2005

Ms. Leslie Young
Regulatory Affairs Associate
International Technidyne Corporation
8 Olsen Avenue
Edison, New Jersey 08820

Re: k050016
Trade/Device Name: HEMOCHRON® Signature Elite™
Regulation Number: 21 CFR § 864.5425
Regulation Name: Multipurpose system for In Vitro coagulation studies
Regulatory Class: II
Product Code: JPA
Dated: January 3, 2005
Received: January 4, 2005

Dear Ms. Young:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050016

Device Name: HEMOCHRON® *Signature Elite*™

Indications for Use:

The HEMOCHRON® *Signature Elite*™ 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 coagulation 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.

For *in vitro* Diagnostic Use Only

Prescription Use XX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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