ITC

K030818
APR 02 2003

510 (k) Summary

HEMOCHRON® Response Instrument/System

Prepared: March 13, 2003

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

Device Name

Common / Usual Name: Whole Blood Coagulation Test System
Product Name: HEMOCHRON® Response Instrument/System

Predicate Device

HEMOCHRON® Response (K983475)

Device Description

The Hemochron Response instrument/system described herein is a software upgrade (Version 2.0) to the current Hemochron Response Instrument, which has been cleared under K983475 (May 1999).

The HEMOCHRON® Response is a portable, dual-well microprocessor-controlled coagulation instrument with an integral barcode reader, laboratory communication interface and a printer 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 modified Response instrument performs the same assays as the predicate instrument. There are no changes to the clot detection algorithm.

The patented clot detection mechanism is an electro-mechanical system consisting of two test wells into which disposable test tube assays are inserted. The test tube assays contain specific reagent for the test performed and a precision magnet. Immediately after adding a blood sample to the test tube and pressing the start button, the test tube is placed in the test well and is automatically rotated at a slow controlled speed and incubated at 37°C. When a fibrin clot begins to form, it causes the magnet in the test tube to be displaced. Two magnetic detectors located in the test well continuously monitor the precise position of the magnet. When a pre-determined displacement occurs, the elapsed time form the start of the test and the clot endpoint is displayed as the coagulation time in seconds.

The HEMOCHRON® Response contains extensive 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
- Printing of results
- Tagging of test results with date and time
- Operator Lockout
- Storage of operator identification numbers
- Downloading of stored patient and QC data to a PC
- Configurable date and time formats

New Features of the Hemochron Response Instrument

The modifications to the Hemochron Response instrument include a software revision to the instrument. The major components of the software modification include the following:

- Activation of the automated heparin and protamine dosing calculations for patient management. This system is the RxDx module and is described in a previous submission **(K010193)** for the Hemochron Kaolin-Activated heparin and protamine dosing assays.
- Enhanced programming capability and flexibility for the user through the use of the instrument keypad and the Hemochron Response Data Management Software (HRDM), which is provided for use in a personal computer (PC). The use of the Hemochron Response Data Management Software has been described in the predicate device submission and operator's manual **(K983475).**

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, the RxDx module and the features associated with the (HRDM).

Statement of Intended Use

The HEMOCHRON ® Response is intended for professional use for hemostasis management in a variety of clinical settings for the quantitative determination of an assortment of coagulation test assays including the following **HEMOCHRON Whole Blood Coagulation Assays for In vitro diagnostic use only.**

Activated Clotting Time (ACT) – All HEMOCHRON types
Activated Partial Thromboplastin Time (APTT) – All HEMOCHRON types
Prothrombin Time (PT) – All HEMOCHRON types
Thrombin Time (TT)
Heparin Neutralized Thrombin Time (HNTT)
High Dose Thrombin Time (HiTT)
Fibrinogen (FIB)
Protamine Dose Assay (PDA) - All HEMOCHRON types
Heparin Response Time (HRT) - All HEMOCHRON types
Protamine Response Time (PRT) - All HEMOCHRON types

Summary of Performance Data

Laboratory Correlations

Laboratory correlation studies were conducted between the Hemochron Response V1.52 (Current Version) and Hemochron Response V2.00 (Modified Version) instruments using a split sample design. Heparin sensitivity testing was conducted on the test tubes from each of three groups of tests, namely ACT (including ACT, KACT and P214), specialty tubes (including APTT FWB, APTT Citrate, PT FWB, PT Citrate, TT, HNTT, HiTT, Fibrinogen diluted and undiluted) and RxDx tubes (including HRTB, HRTP, PDAO, PRT200, PRT400, each in Celite or kaolin versions). Blood samples were drawn from four different donors and heparinized in vitro. Six HR V2.00 and six HR V1.52 were used for these laboratory studies.

The linear correlations between the instruments were excellent.
(Y=HR V2.00, X=HR V1.52) *HR=Hemochron Response*

Test Assay Group	Correlation Equation	r value	n
ACT Tubes	y=0.98x-9.36	0.995	18
Specialty Tubes	y=1.04x-0.45	0.954	15
RxDx Tubes	y=1.00x-16.32	0.998	17

Precision Testing

Precision testing was conducted using two levels of assay-specific controls on two Response V1.52 and two Response V2.00 (n=10 per instrument type) instruments. Representative assays from each of three groups of tests including ACT (ACT test tubes), APTT Fresh Whole Blood, HiTT (Specialty test tubes) and PRT (RxDx test tubes) were used in the test matrix.

Assay: ACT (Control used: CPL Normal and Level II)

Level 1	HR V2.00	HR V1.52
total mean	127.5	130.8
SD	7.6	8.1
CV%	6.0%	6.2%
mean diff	2.52%	

Level 2	HR V2.00	HR V1.52
total mean	269.3	261.8
SD	13.8	9.0
CV%	5.1%	3.4%
mean diff	2.86%	

Assay: APTT FWB (Control used: Q101 Normal and Abnormal)

Level 1	HR V2.00	HR V1.52
total mean	103.5	106.6
SD	7.8	9.1
CV%	7.5%	8.5%
mean diff	2.91%	

Level 2	HR V2.00	HR V1.52
total mean	335.6	321.9
SD	17.9	16.9
CV%	5.3%	5.2%
mean diff	4.26%	

Assay: PRT **(Control used: RxDx WBC Normal and PRT Level II)**

Level 1	HR V2.00	HR V1.52
total mean	151.8	156.5
SD	7.7	8.8
CV%	5.1%	5.6%
mean diff	3.51%	

Level 2	HR V2.00	HR V1.52
total mean	359.5	376.4
SD	14.9	10.3
CV%	4.2%	2.7%
mean diff	4.49%	

Assay: HiTT **(Control used: RxDx WBC Normal and HiTT Level II)**

Level 1	HR V2.00	HR V1.52
total mean	57.1	59.6
SD	8.2	8.0
CV%	14.4%	13.5%
mean diff	4.19%	

Level 2	HR V2.00	HR V1.52
total mean	168.6	183.9
SD	26.4	24.0
CV%	15.7%	13.0%
mean diff	8.32%	

Conclusion of Risk analysis and Design Controls

Based on the extensive verification and validation testing, it can be concluded that the potential risks associated with the modified system have been resolved and that safety and effectiveness of the HEMOCHRON Response Instrument/System are not compromised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 0 2 2003

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

Re: k030818
Trade/Device Name: HEMOCHRON® Response Instrument/System
Regulation Number: 21 CFR § 864.5425
Regulation Name: Multipurpose System for In Vitro Coagulation Instruments
Regulatory Class: II
Product Code: JPA
Dated: March 13, 2003
Received: March 14, 2003

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 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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (If Known): K030818

Device name: HEMOCHRON® Response

Indications for Use:

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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 K030818

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

(Optional Format 1-2-96)