5/3/99

K983475

INTERNATIONAL TECHNIDYNE CORPORATION

Fax

To:	Djuana Blagmon	**From:**	John Clay
Fax:	301-594-5940	**Pages:**	Including cover
Phone:	301-594-1243	**Date:**	April 27, 1999
Re:	K983475 Revised Summary	**CC:**	F. LaDuca, Ph.D

☐ **Urgent** x **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

• **Comments:**

Dear Djuana:

Attached is the revised **510K Summary** including the instrument correlation equations.

The original is being sent to the mail center via UPS. Please replace the previous version sent on April 22, 1999.

If there are any questions, please contact me.

Regards,

John Clay

Regulatory Compliance Officer

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510 (k) Summary HEMOCHRON® Response

Prepared: April 27, 1999

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

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: HEMOCHRON® Response Coagulation Analyzer.
Product Name: HEMOCHRON® Response

Predicate Device

HEMOCHRON® Model 8000 / HEMOCHRON® Models 401 / 801

Device Description

The HEMOCHRON® Response is an upgrade of the HEMOCHRON® Coagulation Instruments, HEMOCHRON® Model 8000 that was approved under 510(k) K930068 and the HEMOCHRON® Models 401 and 801. The HEMOCHRON® Response performs the same tests as the predicate HEMOCHRON® Instruments. All test assays are previously 510(k) approved. The HEMOCHRON® Response employs the same mechanical clot detection system as the predicate HEMOCHRON® Instruments. Mechanical systems can be used to monitor clotting times in either whole blood or plasma samples.

The HEMOCHRON® employs a mechanical clot detection system. The principle of operation is based on the electrical field generated by a magnet contained within a glass test tube when the magnet is in close proximity to the detector located within the test well.

To perform a test, blood is added to the test tube and placed in the test well. The magnet freely rotates within the tube, in a non-clotted sample. The magnet position is detected by two solid-state Hall effect sensors. When a clot forms the magnet is caught within the clot and is shifted out of the detection area. The electrical change that occurs due to the magnet rotation triggers the timer to stop with an audible beep signaling clot formation to the user.

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.

For In Vitro Diagnostic Use Only

Summary of Technological Characteristics and Performance Data

The HEMOCHRON® Response is a software / firmware and mechanical upgrade of the HEMOCHRON® Instruments designed to perform the same tests as the predicate instruments. The upgrade provides the end user with additional quality features not currently available in the predicate HEMOCHRON® Instruments.

The HEMOCHRON® Response is a modification of the HEMOCHRON® Instruments with improved test well operation and reliability through the use of two Hall Effect solid-state detectors. This provides for full magnet position tracking within the test tube and eliminates the calibration drift of well parameters.

In addition a UPC-E bar code detector has been added to automatically read the affixed bar code label and identify the test assay, expiration date and lot number of the test assay. The instrument provides advanced patient and QC data tracking and streamlined computer interface capabilities which provide essential quality features for the end users.

The following is a summary of Clinical and Laboratory data demonstrating substantial equivalence between the HEMOCHRON Response and the predicate HEMOCHRON instrument.

Clinical

Using a split sample design, the data was collected from 42 patients, yielding a total of 242 comparative ACT results. The test results were highly correlated ($r = 0.94$).
$y = 0.912x + 24.77$

Laboratory

Four representative assays were selected to demonstrate substantial equivalence. (ACT, APTT, PT(citrate) and HiTT) In all studies split samples were obtained to run on both the HEMOCHRON Response and the predicate HEMOCHRON.

ACT
An in vitro heparin dose response employing normal donor blood demonstrated the comparable sensitivity of the ACT through the entire reportable range (up to 1000 seconds) of the assay. ($n = 66$, $r = 0.96$) **$y=0.95x + 18.00$**

APTT
An in vitro heparin dose response employing normal donor blood demonstrated the comparable sensitivity of the APTT through the entire reportable range of the assay. ($n = 41$, $r = 0.99$) **$y=1.03x - 4.51$**

PT (citrate)
Comparable PT results using the HEMOCHRON Response and the predicate HEMOCHRON were generated using freshly obtained blood specimens from patients receiving low doses of oral anticoagulant. ($n = 22$, $r = 0.986$) **$y= 1.00x -3.876$**

HiTT
An in vitro heparin dose response employing normal donor blood demonstrated the comparable sensitivity of the HiTT through the reportable range of the assay. ($n = 29$, $r = 0.91$) **$y= 0.89x +20.58$**

Conclusion:

The HEMOCHRON Response is substantially equivalent to the predicate HEMOCHRON instrument. The HEMOCHRON Response system has the same intended use and employs the same assays as the predicate HEMOCHRON.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 3 1999

Mr. John Clay
Regulatory Compliance Officer
International Technidyne Corporation
6 Olsen Avenue
Edison, New Jersey 08820

Re: K983475
Trade Name: HEMOCHRON® Response
Regulatory Class: II
Product Code: KQG, JPA
Dated: February 23, 1999
Received: February 24, 1999

Dear Mr. Clay:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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): K983475

Device name: HEMOCHRON® Response

Indications for 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**

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

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 K983475

Prescription Use ✓ or Over- the- Counter Use ____
Per 21 CFR 801.109 (Optional Format 1-2-96)