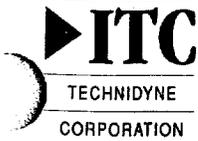


SEP 30 1998



8 Olsen Avenue Edison, NJ 08820

Toll Free Phone: (800) 631-5945

Phone: (732) 548-5700 FAX: (732) 632-9299

K972800

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FDA/CDRH/ODE/DMC

510(k) SUMMARY

Prepared:

March 26, 1998

Submitted by:

Robert Matland
International Technidyne Corporation
23 Nevsky Street
Edison, NJ 08820
Office: 732-548-5700 x 248
Fax: 732-548-2419

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Device Name

PRODUCT NAME:

Hemochron® Jr. Microcoagulation Citrated PT

COMMON/USUAL NAME:

Citrated Whole Blood Prothrombin Time Test

Predicate Device

International Technidyne Corporation Hemochron® Jr. Microcoagulation Prothrombin Time Test, which was approved under 510(k), K940432/S1 dated 5/18/94.

Device Description

The Hemochron® Jr. Microcoagulation Citrated PT test is a self-contained disposable test cuvette, prefilled with dried reagents required to perform a PT using citrated whole blood with the Hemochron® Jr. Whole Blood Microcoagulation System.

The thromboplastin employed in the Hemochron® Jr. Microcoagulation Citrated PT test is identical to that used in the predicate device, the ITC Microcoagulation Prothrombin Time Test. The difference between the current assay and the predicate is a reagent modification to include calcium salt such that citrated whole blood may be used as the test substrate. The predicate device uses only fresh, non-citrated whole blood. In addition to the calcium salt, the preparation contains rabbit brain thromboplastin, stabilizers and buffers, similar to the reagents contained in

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the predicate device. The Hemochron® Jr. Microcoagulation Citrated PT and the predicate ITC Microcoagulation Prothrombin Time Test are both intended for point-of-care use. Both assays are performed using the ITC Microcoagulation analyzers.

The Hemochron® Jr. Microcoagulation Citrated PT and the predicate ITC Microcoagulation ProTime® test are both also substantially equivalent to the standard laboratory plasma PT assay. The results of the Hemochron® Jr. citrated PT are displayed as INR (International Normalized ration). Based on the clinical correlation studies presented in this submission, a conversion of the whole blood PT to the plasma PT is programmed into the instrument and the plasma PT (in seconds) also displayed at the conclusion of the test. In this way, PT results are available to the clinician in familiar plasma equivalent clotting times. The displayed plasma equivalent is at an assumed plasma PT reagent ISI of 1.0.

Statement of Intended Use

The Hemochron® Jr. Microcoagulation Citrated PT is a unitized microcoagulation test intended for in-vitro diagnostic use in performing a quantitative, one-stage prothrombin time for the monitoring of patient receiving oral anticoagulant therapy. The Citrated PT test is performed using a citrated whole blood sample on the Hemochron® Microcoagulation system. The instrument is portable and is intended for point-of-care testing. The instrument is not intended for home use.

Summary of Performance Characteristics

The Hemochron® Jr. Microcoagulation Citrated PT test was evaluated in laboratory studies to establish sensitivity to vitamin K depending coagulation factors. Dose-response curves were obtained for the factors which were highly correlated to the laboratory (plasma-based) assay. As the coagulant factor level decreased below 40% the Citrated PT result began to prolong above normal range. Clinical comparisons to the laboratory assay were conducted at the three university medical centers. These tests demonstrated a high degree of correlation of the Hemochron Jr. Citrated PT-INR result and laboratory PT-INR results. Precision of the assay measured using whole blood controls was between 1% and 7% across different operators and test days.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 30 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Robert Matland
Compliance Officer
International Technidyne Corporation
8 Olsen Avenue
Edison, New Jersey 08820

Re: K972866/S3
Trade Name: HEMOCHRON® Jr. Microcoagulation Citrated PT
Regulatory Class: II
Product Code: GJS
Dated: August 1, 1998
Received: August 6, 1998

Dear Mr. Matland:

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.

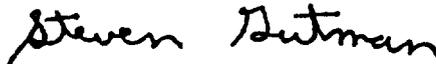
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2

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 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): K972866

Device Name: Hemochron® Jr. Microcoagulation Citrated PT

Indications For Use:

INTENDED USE:

The Hemochron® Jr. Citrated PT is a unitized microcoagulation test intended for in vitro diagnostic use in performing a quantitative, one-stage prothrombin time. The Citrated PT test is performed using a citrated whole blood sample on the Hemochron® Jr. microcoagulation system. The instrument is portable and is intended for point of care testing. The instrument is not intended for home use.

For in vitro Diagnostic Use

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
[Signature]

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K972866

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)