K974799

JUL 7 1998

INTERNATIONAL
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TECHNIDYNE
CORPORATION

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510(k) SUMMARY

Prepared: 1/19/98

Submitted by: Robert Matland
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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.

The assigned 510(k) number is K974799.

Device Name

Common/Usual Name: HEMOCHRON® Jr. Generation II Microcoagulation System

Product Name: HEMOCHRON® Jr. Generation II
HEMOCHRON® Jr. Signature

Predicate Device

International Technidyne Corp. HEMOCHRON® Jr. Microcoagulation System which was approved under 510(k) K923761/A (APTT only, January 21, 1993) and K940401 (multiple assay use May 11, 1994).

Device Description

The Generation II system performs the same tests as the predicate Jr. system, APTT, PT, ACT+, and ACT-LR with the same end point detection system. All assays are intended to be performed at point of care (POC). Blood is placed in a collection reservoir of the test cuvette and automatically sampled into a test channel which contains reagents required to perform the respective assay. Excess blood is drawn into a waste cuvette. The clot detection mechanism is a combination mechanical-optical system. As blood is actively pumped back and forth in the test channel, two LED detectors measure the position of the blood. As clotting occurs, the movement of the blood decreases below a pre-determined rate and an endpoint is recorded. Test results for the APTT and PT are displayed as whole blood clotting times and plasma equivalent times. Test results for the ACT+ and ACT-LR are displayed as traditional HEMOCHRON® celite ACT values.

Statement of Intended Use

The portable, battery operated HEMOCHRON® Jr. Generation II and Signature are microcoagulation instruments designed to perform whole blood coagulation tests using fresh whole blood at the point-of-care. The system is intended to be used in numerous clinical settings requiring point-of-care testing. Test results are displayed as whole blood test results and plasma equivalent values, in seconds. For the ACT, the instrument also displays correlated celite equivalent values. The APTT and PT correlated values are based on regression analyses of comparative whole blood/plasma studies.

Summary of Technological Characteristics

The upgrade for which this 510(k) is intended is the incorporation into the Generation II system of advanced program capability and interface capability with a PC(personal computer). These features allow the user to execute a number of software functions which specifically:

1. Allow users to screen the test operators and provide or limit system access. This is provided in response to clinical user's desire to monitor quality assurance and execute specific operator lockout.

2. Allow users to input specific performance ranges into the device for specific assays. With this feature users are able to utilize institution-specific correlations of the HEMOCHRON® Jr. POC test (i.e., APTT or PT) to the local laboratory.

3. Allow users to download data from the individual systems to a computer system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 7 1998

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

Re: K974799
HEMOCHRON® Jr. Generation II, HEMOCHRON® Jr. Signature
Regulatory Class: II
Product Code: JPA
Dated: April 23, 1998
Received: May 12, 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 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.

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 "dsmo@fdadr.cdrh.fda.gov".

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

VRD

510(k) Number (if known): K974799

Device Name: HEMOCHRON® JR. GENERATION II
HEMOCHRON® JR. SIGNATURE

Indications For Use:

The portable, battery operated HEMOCHRON® JR. SIGNATURE is a microcoagulation instrument designed to perform whole blood coagulation tests using fresh whole blood at the patient bedside. The system is intended to be used in many clinical settings requiring point-of-care testing. Whole blood test results are displayed as clotting times, in seconds. The instrument also displays correlated celite equivalent values. The correlated values are based on regression analyses of comparative whole blood/plasma studies.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K974799

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)