4/13/99

K990449

510 (k) Summary

HEMOCHRON® Electronic System Verification Tube

Prepared: February 10, 1999

Submitted by: John Clay
International Technidyne Corp.
6 Olsen Ave.
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® Electronic Quality Control (EQC)

Product Name: HEMOCHRON® Electronic System Verification Tube (ESVT)

Predicate Device

HEMOCHRON® Verify System / Factor VI Qualify System (K940957/S1)

Device Description

The Electronic System Verification Tube (ESVT) performs Electronic Quality Control on all marketed HEMOCHRON® tube instruments HEMOCHRON® models 8000, 401, 801 and the new HEMOCHRON® *RESPONSE* (K983475) currently under FDA review.

The device is a plastic tube with battery operated electronic circuitry that electronically simulate test initiation and clot detection using the same principles employed in a clotting time assay. Once started and placed in the Hemochron test well, the ESVT electronically simulates the operation of a 100, 300 and 500 second clotting time.

The comparison of the displayed Hemochron clotting time with the ESVT clotting time is a quality control test of the functionality of the test well and test detector.

Statement of Intended Use

The HEMOCHRON® Electronic System Verification Tube is intended for in vitro diagnostic use in performing a quantitative electronic detection system verification of HEMOCHRON® Coagulation Instruments. The Electronic System Verification Tube electronically simulates test initiation and clot detection in the same manner as patient assay end points are recorded.

Summary of Technological Characteristics and Performance Data

The HEMOCHRON® ESVT is an improvement to the Electronic Quality Control designed to perform the same three (3) testing time ranges as the predicate three (3) separate electronic verification tubes. The upgrade provides the end user with additional quality features to assure the HEMOCHRON® instrument is operating properly. The ESVT is designed to check the timing capability of the HEMOCHRON instrument, as well as, verifying well rotation.

The previously approved test ranges are established in (K940957/S1).

Specifications

Control	Acceptable range
Normal level	90-110 seconds
Abnormal level I	290–310 seconds
Abnormal Level II	490-510 seconds

Precision was validated using three different operators on all HEMOCHRON® models (401, 801, 8000, Response) over a minimum of three days. The precision study data are summarized below.

Normal			Abnormal 1			Abnormal 2	
Mean	97.56		Mean	297.3		Mean	497.6
SD	2.67		SD	3.03		SD	3.11
CV%	2.74		CV%	1.02		CV%	0.63
N	120		N	120		N	120

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administratio
9200 Corporate Boulevard
Rockville MD 20850

APR 13 1999

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

Re: K990449
Trade Name: HEMOCHRON® Electronic System Verification Tube (ESVT)
Regulatory Class: II
Product Code: JPA
Dated: February 10, 1999
Received: February 12, 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): K990449

Device name: HEMOCHRON ® Electronic System Verification Tube

Indications for Use:

The HEMOCHRON® Electronic System Verification Tube is intended for in vitro diagnostic use in performing a quantitative electronic detection system verification of HEMOCHRON® Coagulation Instruments. The Electronic System Verification Tube electronically simulates test initiation and clot detection in the same manner as patient assay end points are recorded.

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)

Peter E. Maheux

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990449

Prescription Use ✓
Per 21 CFR 801.109

or

Over- the- Counter Use_____

(Optional Format 1-2-96)