OCT 6 - 2004

K042270

510(k) Notification
Premarket Notification [510(k)] Submission
Stat K In Vitro Diagnostic Test System

ATTACHMENT II. 510(k) SUMMARY
[As required by 21 CFR 807.87(h)]

Introduction

According to the requirements of 21 CFR §807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Identification of Submitter [21 CFR §807.92(a)(1)]

Submitter:	Martin J. Patko Vice President of Research and Development StatChem, Inc. 619 North Poplar St. Orange, CA 92868
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E-Mail:	mpatko@att.net
Date of preparation:	August 20, 2004

Identification of the Device [21 CFR §807.92(a)(2)]

Device Proprietary Name:	Stat K In Vitro Diagnostic Test System
Common Name:	Potassium Test System
Classification Name:	In Vitro Diagnostic Potassium Test System (per 21 CFR 862.1600)

Marketed Devices to Which Equivalence is Claimed [21 CFR §807.92(a)(3)]

Device:	Stat K System
Manufacturer:	Portable Diagnostic Services, Inc.
510(k) Number:	K915345
Device:	SYNCHRON CX5® SYSTEM
Manufacturer:	Beckman Coulter, Inc.
510(k) Number:	K011465
Device:	Corning 614 Na/K Analyzer
Manufacturer:	Corning Medical & Scientific
510(k) Number:	K843530

ATTACHMENT II. 510(k) SUMMARY (Continued) [As required by 21 CFR 807.87(h)]

Description of Device [21 CFR §807.92(a)(4)]

Stat K In Vitro Diagnostic Test System is a medical device used for the in vitro diagnostic measurement of Potassium in venous whole blood. The device consists of a battery operated hand-held Analyzer and a precalibrated and disposable Sensor cartridge. While basically a standard electrochemical device that employs a sensing membrane embedded with the potassium selected ligand Valinomycin, Stat K differs from other similar devices in several important ways.

The Sensor cartridge is liquid-free allowing storage at room temperature for several months without degradation of performance. The Sensor cartridge is precalibrated at the factory thus requiring no operator interaction to perform calibration. The Sensor cartridge is designed for single use only. This device is exceptionally simple to use as the operator is required to perform four elementary steps to complete the test: (1) Insert Sensor Cartridge, (2) Peel Sensor cap when prompted, (3) Apply blood sample when prompted, and, (4) Read results on LCD display.

The Stat K Potassium Sensor uses an ion selective membrane to determine the concentration of potassium ions in solution. The physical structure of the potassium selective Valinomycin membrane is such that the complexing sites on the membrane selectively bind to the Potassium ion. When complexing occurs, an electrical potential is generated proportional to the logarithm of the potassium ion concentration in the sample. The concentration of Potassium ion is calculated from the electrode potential by use of the Nernst Equation.

Calibration of the *Stat K In Vitro Diagnostic Test System* is automatically performed immediately prior to each potassium determination. Each Potassium Sensor contains a calibration material with a predetermined concentration of Potassium.

Intended Use [21 CFR §807.92(a)(5)]

The StatChem Stat K is a device intended to measure potassium in venous whole blood. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels. The Stat K may be used for adult or pediatric venous whole blood samples. It may be used by a central laboratory or at point of care sites.

The intended use statement for the *Stat K In Vitro Diagnostic Test System* differs from the indended use statement from that of the legally marketed predicate devices in that the *Stat K In Vitro Diagnostic Test System* measures potassium levels in venous whole blood. Thus, new issues of safety and effectiveness of *Stat K In Vitro Diagnostic Test System* are not introduced.

ATTACHMENT II. 510(k) SUMMARY (continued) [As required by 21 CFR 807.87(h)]

Summary of Technological Characteristics in Comparison to the Predicate Devices [21 CFR §807.92(a)(6)]

The *Stat K In Vitro Diagnostic Test System* employs nearly identical technological characteristics as the Portable Diagnostic Services Stat K predicate device. A comparison of the similarities and differences of the Stat K In Vitro Diagnostic Test System with that of the predicate devices are provided in Table 1, below.

TABLE 1. SIMILARITIES AND DIFFERENCES

DEVICE	PORTABLE DIAGNOSTICS STAT K	STATCHEM STAT K	BECKMAN COULTER CX5 PRO	CORNING 614 NA/K ANALYZER
Intended Use	Potassium Measurement	Potassium Measurement	Multiple	Multiple
Measurement Principle	Electrochemical	Electrochemical	Electrochemical	Electrochemical
Measuring Range	2.0 – 8.0 mEq/L	~~3.00 – 7.00~~ mEq/L 2.00 – 8.00	3.6 – 5.0 mEq/L	0.50 – 9.99 mEq/L
Specimen Type	Whole Blood, Serum or Plasma	Venous Whole Blood	Serum, Plasma or Urine	Whole Blood, Serum, or Urine
Analyzer Features:				
Power Source	Battery Operated	Battery Operated	Alternating Current	Alternating Current
Hand held	Yes	Yes	No	No
Batter operated	Yes	Yes	No	No
Display	Liquid Crystal	Liquid Crystal	Liquid Crystal	Vacuum Fluorescent Display
Analyzer/ Cartridge Interface	Bar Code	Semiconductor Element	Does not apply	Does not apply
Temperature Compensated	Yes	Yes	Yes	Yes
System Control	Microprocessor	Microprocessor	Microprocessor	Microprocessor
Cartridge Features:				
Sensing Membrane	Gel based	Plastic Polymer	Solvent based	Solvent based
Calibration Membrane	Gel based	Gel based	None	None
Single Use	Yes	Yes	Batch	Batch
Shelf Life	18 Months	18 Months	Not Applicable	Not applicable

ATTACHMENT II. 510(k) SUMMARY (continued) [As required by 21 CFR 807.87(h)]

Summary of Non-Clinical Tests Submitted [21 CFR §807.92(b)(1)]

Stat K In Vitro Diagnostic Test System measurements are performed on venous whole blood specimens and have been calibrated to agree with standard laboratory and reference methods. The *Stat K In Vitro Diagnostic Test System* uses undiluted electrochemical methods which may differ from those obtained by indirect or diluted methods (N.W. Tiez, E.L. Pruden, O. Siggaard-Anderson, "Electrolytes" In Tiez Textbook of Clinical Chemistry – Second Edition, C.A. Burtis and E.R. Ashwood, eds. Philadelphia: W.B. Saunders Company, 1994). Moreover, the user is cautioned to perform Potassium testing with the *Stat K In Vitro Diagnostic Test System* using free flowing venous blood only.

The equivalence of the *Stat K In Vitro Diagnostic Test System* to both the Corning 614 and the Beckman Coulter SYNCRON CX5 PRO System was established on the basis of pre-clinical testing. Testing was performed in the hands of intended users at various point-of-care facilities and at the laboratory facility of StatChem Inc., located in Orange, California. Precision performance experiments were based on NCCLS EP5-A, *Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline*. Method comparison experiments were based on an experimental design modeled after NCCLS EP9-A2, *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second Edition*.

Precision performance was characterized using both aqueous solutions of known potassium concentrations and venous whole blood samples. Precision performance data indicate that the performance of the *Stat K In Vitro Diagnostic Test System* is substantially equivalent to both the Corning 614 and the Beckman Coulter SYNCRON CX5 PRO System.

Method comparison experiments were conducted comparing the *Stat K In Vitro Diagnostic Test System* to the both the Corning 614 Na/K Analyzer and the Beckman Coulter SYNCRON CX5 PRO System. The resulting linear regression line comparing the *Stat K In Vitro Diagnostic Test System* to the Corning 614 is: Stat K = 0.12 + 0.97 Corning 614. The resulting linear regression line comparing the *Stat K In Vitro Diagnostic Test System* to the Beckman Coulter SYNCRON CX5 PRO System is: Stat K = 0.08 + 1.02 Beckman CX5. Method comparison data indicate that the performance of the *Stat K In Vitro Diagnostic Test System* is substantially equivalent both the Corning 614 and the Beckman Coulter SYNCRON CX5 PRO System.

In summary, the *Stat K In Vitro Diagnostic Test System* is substantially equivalent to the three predicate devices.

ATTACHMENT II. 510(k) SUMMARY (continued) [As required by 21 CFR 807.87(h)]

Interfering Substances

In vitro diagnostic tests of all types are potentially perturbed by the interference of certain endogenous substances and drugs found in the blood of individuals being tested. During the evaluation of the predicate device, Portable Diagnostic Services' Stat K System, such phenomena were rigorously studied for important endogenous substances and drugs encountered (see FDA 510(k) number K915345). Ion selective electrodes, because of very high analyte selectivity, are generally resistant to such interference (N.W. Tiez, E.L. Pruden, O. Siggaard-Anderson, "Electrolytes" In Tiez Textbook of Clinical Chemistry - Second Edition, C.A. Burtis and E.R. Ashwood, eds. Philadelphia: W.B. Saunders Company, 1994), as was the Portable Diagnostic Services' Stat K System predicate device, and thus *Stat K In Vitro Diagnostic Test System*.

Conclusions Drawn from Non-Clinical Tests Submitted [21 CFR §807.92(b)(3)]

Non-clinical tests performed by medical professionals under conditions expected to simulate actual use conditions using the *Stat K In Vitro Diagnostic Test System* support a claim of substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 6 - 2004

Mr. Martin J. Patko
Vice President of Research and Development
StatChem, Inc.
619 North Poplar Street
Orange, CA 92868

Re: k042270
Trade/Device Name: Stat K In Vitro Diagnostic Test System
Regulation Number: 21 CFR 862.1600
Regulation Name: Potassium
Regulatory Class: Class II
Product Code: CEM
Dated: August 20, 2004
Received: August 23, 2004

Dear Mr. Patko:

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,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
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Enclosure

Indications for Use

510(k) Number (if known): K042270

Device Name: Stat K In Vitro Diagnostic Test System

Indications For Use:

The StatChem Stat K is a device intended to measure potassium in anticoagulated venous whole blood and assayed within twenty minutes of collection. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels. It may be used by a central laboratory or at point of care sites.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K042270