K042191

DIAZYME

OCT 2 9 2004

Summary

Submitter's name: Diazyme Laboratories Division, General Atomics

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Date the summary was prepared: August 9, 2004

Name of the device: Potassium Enzymatic Assay
Trade Name: Diazyme Potassium Enzymatic Assay
Common/Usual Name: Enzymatic Assay, Potassium
Classification Name: Electrode, Ion Specific, Potassium
Device Class: II

Predicate Device:

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]: Synchron LX I 725 Clinical System (K023049) manufactured by Beckman Coulter Inc., Brea, CA, USA.

Description of the devices

In healthy individual, an extracellular fluid level of potassium is regulated to maintain at 3.5-5.5mM. Small deviations from normal level can have severe health consequences. Monitoring serum potassium concentration is important in both routine check and emergency rooms. Currently, the two most commonly used methods to detect serum potassium are ion-selective electrode (ISE) and flame photometry. However, routine maintenance of these analyzers requires much effort and sometimes would be cumbersome. Diazyme's Potassium Enzymatic assay is proven to be equivalent to ISE method but more user friendly in automated analyzers.

Potassium is determined spectrophotometrically through a kinetic coupling assay system using potassium dependent urea amidolyase (UAL). NADH generated in a coupling enzymatic reaction reduces a water soluble colorless tetrazolium salt, WST-1 in the presence of an electron

mediator, 1-methoxy-5-methyl-phenazinium methyl sulfate (PMS), to form a water soluble formazan dye, which has a maximum absorbance at 450 nm. The corresponding increase of optical density at 450 nm is proportional to the potassium concentration in the serum

Intended Use of the Device:

Diazyme Potassium Enzymatic Assay Kit in conjunction with Diazyme Potassium Low and High Calibrators, are intended for the quantitative determination of Potassium (K) in serum.

Performance Characteristics

Diazyme's Potassium Enzymatic Assay is a two reagent (R1 and R2) based kinetic assay system. The results are obtained in 15 min by measuring absorbance at 450 nm. No off line pretreatment is needed. The assay has a wide measuring range from 2 to 8 mmol/L of serum potassium. The assay offers excellent precision as shown in the table below:

	4.4mM K^+	6.4mM K^+
Within Precision	CV%=3.2%	CV%=3.0%
Total Precision	CV%=5.3%	CV%=3.3%

Diazyme's Potassium Enzymatic assay has a good correlation with Synchron LX I 725 Clinical System with a correlation coefficient of 0.96. The average analytical recoveries for potassium added to two different sera were 104% and 97% respectively. We have conducted interference study by spiking the substances to be tested to the pooled human sera and found little interference at the indicated concentrations:

Interference	Concentration
NH_4Cl	1 mM
NaPi	1.5 mM
$CaCl_2$	5 mM
NaCl	200 mM
$CuCl_2$	0.25 mM
$ZnCl_2$	0.25 mM
$FeCl_3$	0.025 mM
Ascorbic Acid	5 mM
Glucose	5 mM
Bilirubin	10mg/dl

Conclusion: Comparison analysis presented in the 510K submission for this device in the comparison section, together with linearity, precision and interference study presented demonstrated that the Diazyme's Potassium Enzymatic Assay has excellent accuracy and is safe and effective. There is no significant deviation between the results obtained by Diazyme's Potassium Enzymatic Assay and legally marketed predicate when testing clinical patient serum

samples Therefore, Diazyme's Potassium Enzymatic Assay is substantially similar to the commercially available products to measure potassium levels in human serum samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 2 9 2004

Mr. Huan Tran
Quality Assurance Manager
Diazyme Laboratories
Division of General Atomics
3550 General Atomics Court
San Diego, CA 92121

Re: k042191
Trade/Device Name: Diazyme Potassium Enzymatic Assay Kit
Diazyme Enzymatic Potassium Serum Controls
Regulation Number: 21 CFR 862.1600
Regulation Name: Potassium test system
Regulatory Class: Class II
Product Code: MZV, JJX
Dated: August 9, 2004
Received: August 12, 2004

Dear Mr. Tran:

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

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
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042191

Device Name: Diazyme Potassium Enzymatic Assay Kit

Indications for Use:

Diazyme Potassium Enzymatic Assay Kit in conjunction with Diazyme Potassium Low and High Calibrators, are intended for the quantitative determination of sodium (K) in serum.

Diazyme Potassium Enzymatic Assay Kit contains a low level standard and a high level standard. The standards are used to generate a linear graph that will be used in the calculation of potassium concentrations in unknown serum samples.

Diazyme Potassium Enzymatic Assay has controls for normal serum potassium level and abnormal serum potassium level. The controls are used as reference samples for checking the functionality of the Diazyme Potassium Enzymatic Assay.

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) K042191