K992845

OCT 18 1999

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Summary of 510(k) Safety and Effectiveness Information

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.

HiChem® Calibrators 1, 2 and 3 are intended to calibrate the Beckman® SYNCHRON CX® DELTA and CX® CE® Systems for the quantitative determination of sodium, potassium, chloride, urea, glucose, creatinine, calcium and total CO2. The HiChem® Calibrator 1 Kit, Calibrator 2 Kit and Calibrator 3 Kit are substantially equivalent to the SYNCHRON® CX® Calibrators 1, 2 & 3, product nos. 465908, 465909 and 465910, manufactured by Beckman Coulter, Inc.

The effectiveness of the HiChem® Calibrators 1, 2 and 3 is shown by the following method comparison studies.

Method Comparison

Serum, plasma, urine and CSF were collected from adult patients and assayed using HiChem® and Beckman® calibrators, reagents and wash solutions on a SYNCHRON CX® DELTA System. Results were compared by least squares linear regression and the following statistics were obtained.

				Regression Statistics			Summary Statistics		
Analyte	Specimen	Unit	n	a	b	r	range	mean X	mean Y
Calcium	Serum/Plasma	mg/dL	160	0.0	0.989	0.985	7.1 - 10.6	9.26	9.13
	Urine	mg/dL	74	-0.2	1.007	0.998	2.4 - 15.2	8.45	8.3
Chloride	Serum/Plasma	mmol/L	160	1.0	0.988	0.935	98.2 - 127.5	107.3	107.0
	Urine	mmol/L	78	-5.1	1.049	0.999	22.4 - 289	126.8	127.9
	CSF	mmol/L	44	-3.4	1.024	0.985	113.8 - 152.4	126.5	126.1
Potassium	Serum/Plasma	meq/L	160	0.13	0.969	1.000	3.20 - 10.82	5.02	5.00
	Urine	meq/L	80	0.01	0.993	1.000	3.48 - 136.0	50.5	50.2
Sodium	Serum/Plasma	meq/L	160	9.1	0.930	0.938	131.8 - 159.1	141.0	140.3
	Urine	meq/L	78	-0.3	1.000	1.000	16.9 - 288.1	118.2	117.8
Total CO_2	Serum/Plasma	mmol/L	160	1.2	0.949	0.953	9.5 - 29.1	23.3	23.2
BUN	Serum/Plasma	mgN/dL	160	-0.3	0.987	0.999	4 - 126	19.0	18.4
	Urine	mgN/dL	79	0.9	0.979	1.000	6 - 142	76.2	75.4
Glucose	Serum/Plasma	mg/dL	159	-1.2	1.011	0.999	29 - 341	100.7	100.6
	Urine	mg/dL	81	-2.1	1.012	0.999	1 - 359	197.3	197.4
	CSF	mg/dL	45	1.0	0.973	0.999	3 - 186	81.9	80.7
Creatinine	Serum/Plasma	mg/dL	160	0.0	0.991	0.997	0.4 - 5.4	1.09	1.08
	Urine	mg/dL	79	-0.3	1.000	1.000	12.1 - 309.2	112.5	112.3

Wynn Stocking

Wynn Stocking
Manager of Regulatory Affairs
Elan Diagnostics

20 August, 1999

Elan Diagnostics
is a division of Elan Pharmaceuticals

Elan Diagnostics
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 18 1999

Mr. Wynn Stocking
Manager, Regulatory Affairs
Elan Diagnostics
231 North Puente Street
Brea, California 92821

Re: K992845
Trade Name: HiChem® Calibrator 1 Kit, Calibrator 2 Kit and Calibrator 3 Kit
Regulatory Class: II
Product Code: JIX
Dated: August 20, 1999
Received: August 24, 1999

Dear Mr. Stocking:

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): K992845

Device Names: HiChem® Calibrator 1 Kit,
HiChem® Calibrator 2 Kit, and
HiChem® Calibrator 3 Kit

Indications for Use:

HiChem® Calibrators 1, 2 and 3 are intended to calibrate the Beckman® SYNCHRON CX® DELTA and CX® CE® Systems for the quantitative determination of sodium, potassium, chloride, urea, glucose, creatinine, calcium and total CO2.

HiChem® Calibrators 1, 2 and 3 for the SYNCHRON CX® DELTA and CX® CE® Systems are intended to establish points of reference that are used in the determination of values in the measurement of substances in specimens.

These calibrators are intended for professional use only.

Respectfully,

Wynn Stocking

Wynn Stocking
Regulatory Affairs Manager
Elan Diagnostics

20 August, 1999

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(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992845

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)