K992847

OCT 14 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® BUN Reagent is intended for the quantitative determination of urea nitrogen in serum, plasma and urine on the Beckman® SYNCHRON CX® and CX® DELTA Systems. The HiChem® BUN Reagent Kit is substantially equivalent to the SYNCHRON® CX® Systems BUN Reagent Kit, product no. 443350, manufactured by Beckman Coulter, Inc.

The effectiveness of the BUN Reagent Kit is shown by the following studies.

Precision:

Control sera and diluted urine pools were each assayed twice per day in triplicate using both HiChem® and Beckman® BUN reagents on a SYNCHRON CX® DELTA System. Data were collected on ten different days over a thirty day period. Estimates of within run and total imprecision were calculated analogous to the method described in NCCLS publication EP3-T.

Precision of BUN Recoveries (mgN/dL)

	HiChem® Reagent						Beckman® Reagent					
			Within Run		Total				Within Run		Total	
Sample	n	mean	1SD	%CV	1SD	%CV	n	mean	1SD	%CV	1SD	%CV
Serum 1	60	7.1	0.65	9.1%	0.66	9.4%	60	7.1	0.65	9.1%	0.60	8.4%
Serum 2	60	35.4	0.62	1.8%	0.66	1.9%	60	35.5	0.53	1.5%	0.57	1.6%
Serum 3	60	63.8	0.50	0.8%	0.80	1.3%	60	64.6	0.72	1.1%	0.76	1.2%
Urine 1	60	21.7	0.89	4.1%	0.82	3.8%	60	21.7	0.62	2.9%	0.63	2.9%
Urine 2	60	112.2	0.75	0.7%	1.25	1.1%	60	114.3	0.82	0.7%	1.31	1.2%

Two control sera were spiked with urea and assayed as described above using ORDAC sample dilution.

Precision of ORDAC BUN Recoveries (mgN/dL)

	HiChem® Reagent						Beckman® Reagent					
			Within Run		Total				Within Run		Total	
Sample	n	mean	1SD	%CV	1SD	%CV	n	mean	1SD	%CV	1SD	%CV
Serum 1	60	179	1.18	0.7%	2.58	1.4%	60	180.0	1.18	0.7%	2.17	1.2%
Serum 2	60	258	1.91	0.7%	3.55	1.4%	60	262.4	1.75	0.7%	2.78	1.1%

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Patient Comparison

Serum and plasma specimens, and urine specimens diluted with 9 parts normal saline, were collected from adult patients and assayed for urea nitrogen on a SYNCHRON CX® DELTA System using HiChem® and Beckman® BUN reagents. Results were compared by least squares linear regression and the following statistics were obtained.

Serum/Plasma Comparison

HiChem® = -0.3 mgN/dL + 0.987 x Beckman® Reagent

r = 0.999 n = 160 range = 4 - 126 mgN/dL

Urine Comparison

HiChem® = 0.9 mgN/dL + 0.979 x Beckman® Reagent

r = 1.000 n = 79 range = 6 - 142 mgN/dL

Wynn Stocking
Manager of Regulatory Affairs
Elan Diagnostics

20 August, 1999

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 14 1999

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

Re: K992847
Trade Name: HiChem® BUN Reagent
Regulatory Class: II
Product Code: LFP
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): K992847

Device Name: HiChem® BUN Reagent

Indications For Use:

HiChem® BUN Reagent is intended for the quantitative determination of urea nitrogen in serum, plasma and urine on the Beckman® SYNCHRON CX® and CX® DELTA Systems.

Urea nitrogen results are used in the treatment of numerous renal and metabolic diseases.

This reagent is intended for professional use only.

Respectfully,

Wynn Stocking

Wynn Stocking
Regulatory Affairs Manager
Elan Diagnostics

20 August, 1999

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992847

(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)