

OCT 18 1999

élan diagnostics



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® Total Protein Reagent is intended for the quantitative determination of total protein in serum and plasma on the SYNCHRON CX® Systems and serum, plasma and cerebrospinal fluid on the SYNCHRON CX® DELTA Systems. The HiChem® Total Protein Reagent Kit is substantially equivalent to the SYNCHRON® CX® Systems Total Protein Reagent Kit, product no. 450224, manufactured by Beckman Coulter, Inc.

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

Precision:

Serum and cerebrospinal fluid controls were each assayed 3 times per day over 10 days using HiChem® and Beckman® total protein reagents on a SYNCHRON CX® DELTA System. Estimates of within run and total imprecision were calculated as described in NCCLS publication EP3-T.

Precision of Total Protein Recoveries

Sample	unit	n	mean	HiChem® Reagent				n	mean	Beckman® Reagent			
				Within Run		Total				Within Run		Total	
				1SD	%CV	1SD	%CV			1SD	%CV	1SD	%CV
Serum 1	g/dL	60	3.8	0.04	1.1%	0.06	1.7%	60	3.8	0.04	1.2%	0.05	1.3%
Serum 2	g/dL	60	5.9	0.04	0.7%	0.08	1.3%	60	5.9	0.04	0.8%	0.06	1.0%
Serum 3	g/dL	60	8.0	0.05	0.7%	0.11	1.4%	60	8.0	0.05	0.6%	0.09	1.1%
CSF 1	mg/dL	60	21	3.17	15.2%	4.11	19.7%	60	21	1.09	5.2%	2.58	12.2%
CSF 2	mg/dL	60	53	1.62	3.1%	2.31	4.4%	60	54	1.52	2.8%	2.79	5.2%

Patient Comparison:

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

Serum/Plasma Comparison

$$\text{HiChem}^\circ = 0.2 \text{ g/dL} + 0.970 \times \text{Beckman}^\circ \text{ Reagent}$$

r = 0.988      n = 160      range = 4.6 - 8.6 g/dL

CSF Comparison

$$\text{HiChem}^\circ = -2.8 \text{ mg/dL} + 1.010 \times \text{Beckman}^\circ \text{ Reagent}$$

r = 0.995      n = 40      range = 11 - 332 mg/dL

Wynn Stocking  
 Manager of Regulatory Affairs  
 Elan Diagnostics

20 August, 1999



DEPARTMENT OF HEALTH & HUMAN SERVICES

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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: K992846  
Trade Name: HiChem<sup>®</sup> Total Protein Reagent  
Regulatory Class: II  
Product Code: CEK  
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.

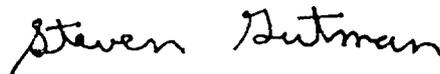
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 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):

K992846

Device Name:

HiChem® Total Protein Reagent

Indications For Use:

HiChem® Total Protein Reagent is intended for the quantitative determination of total protein in serum and plasma on the SYNCHRON CX® Systems and serum, plasma and cerebrospinal fluid on the SYNCHRON CX® DELTA Systems.

Total protein results are used in the diagnosis and treatment of a variety of diseases involving the liver, kidney, or bone marrow as well as other metabolic or nutritional disorders.

This reagent is intended for professional use only.

Respectfully,

*Wynn Stocking*

Wynn Stocking  
Regulatory Affairs Manager  
Elan Diagnostics

20 August, 1999

*Sean Cooper*  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K992846

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(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)