

MAY 19 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 21 CFR 807.92.

Elan ALP Reagent is intended for the quantitative determination of alkaline phosphatase in serum and plasma for the diagnosis and treatment of liver, bone, parathyroid, and intestinal disorders.

The Elan ALP Reagent determines alkaline phosphatase by catalyzing the hydrolysis of p-nitrophenylphosphate to p-nitrophenol. The resulting increase in absorbance at approximately 410 nm is proportional to the alkaline phosphatase activity in the sample.

The Elan ALP Reagent is an adaptation of the AACC and IFCC methods, and is intended for use with the Beckman Synchron CX-5 Autoanalyzer, or with analyzers which can automate the required manipulations. To support this latter use, procedure supplements (application sheets) will be supplied to the users of those instruments.

The Elan ALP Reagent is substantially equivalent to the Beckman[®] SYNCHRON[®] Systems ALP Reagent, product no. 442670, manufactured by Beckman[®] Instruments, Brea, CA. Both reagents are based on the same methodology which determines alkaline phosphatase by the hydrolysis of p-nitrophenylphosphate to p-nitrophenol.

The effectiveness of the Elan reagent application for the Beckman[®] SYNCHRON CX[®] Systems is shown by the recovery of linearity standards, the precision of control recoveries, the recovery of serum controls for on-board stability claims, the validation of chemical additives, and sensitivity claims, and the comparison of patient specimen recoveries to the Beckman[®] SYNCHRON[®] Systems ALP Reagent.

The recoveries of alkaline phosphatase using the Elan ALP Reagent on the SYNCHRON CX[®] Systems are linear from 5 U/L to 1000 U/L as shown by the recovery of linearity standards which span the linearity range. Regression statistics, comparing mean standard recoveries which range from 2 to 1240 U/L, and standard factors which range from 0 to 1251 U/L, are shown below.

$$(\text{Elan Recoveries}) = 2.788 \text{ U/L} + 0.990 \times (\text{Standard Factors}), r^2 = 1.000 \quad s_{(y,s)} = 1.148, \quad df = 10$$

Precision, demonstrated by replicate assays of commercially available control sera and a spiked high control is shown below.

Specimen	n	mean	within-run SD	total SD
low	60	37.5 U/L	1.34	1.36
medium	60	251.4 U/L	1.38	3.70
high	60	740.6 U/L	4.13	15.38

510(k) Notification, Elan Alkaline Phosphatase Reagent Kit
 Elan Diagnostics, Brea, California

24 March, 1999

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Alkaline phosphatase recoveries of 80 serum specimens and 78 plasma specimens are compared between the Elan and Beckman[®] AP Reagents on the SYNCHRON CX[®] Systems. Least squared regression statistics are shown below.

Patients Comparisons:

$$(\text{Elan Results}) = -0.451 \text{ U/L} + 0.9986 \times (\text{Beckman}^{\text{®}} \text{ Results}) \quad r^2 = 0.9964 \quad s_{(y,x)} = 3.059 \quad n = 158$$

The use of anticoagulants, heparin and lithium iodoacetate are shown to be acceptable chemical additives by comparison of spiked and unspiked serum pools. In all cases, the bias due to the addition of anticoagulants is less than 1.5 U/L alkaline phosphatase and statistically insignificant.

The detection limit claim of 5 U/L is documented through the repetitive assay of an alkaline phosphatase standard. The observed detection limit, calculated as three standard deviations of a 30 replicate within run precision study is 1.845 U/L and is below the claimed limit.

The 10 day on-board reagent stability claim is documented through the assay of serum controls over the claimed periods. In all cases, the changes in alkaline phosphatase recoveries over the test periods are less than 3 U/L or 6 %.

510(k) Notification, Elan Alkaline Phosphatase Reagent Kit
Elan Diagnostics, Brea, California



DEPARTMENT OF HEALTH & HUMAN SERVICES

MAY 19 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Ralph Bolstad
Senior R & D Chemist
Elan Diagnostics
231 North Puente Street
Brea, California 92821

Re: K991387
Trade Name: Elan Alkaline Phosphate Reagent Kit
Regulatory Class: II
Product Code: CJE
Dated: April 19, 1999
Received: April 21, 1999

Dear Mr. Bolstad:

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.

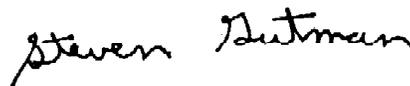
Page 2

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):

Device Name: Elan ALP Reagent Kit

Indications For Use:

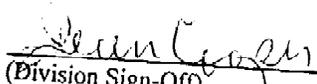
Elan ALP Reagent is intended for the quantitative determination of alkaline phosphatase in serum and plasma for the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

This reagent is intended to be used on a Beckman® SYNCHRON CX® autoanalyzer in a professional setting or by trained personnel, and is not intended for home use.

Respectively,

Ralph Bolstad
Senior R&D Chemist
Elan Diagnostics

19 April, 1999



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 991387

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

Concurrence of CDRII, Office of Device Evaluation (ODE)

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

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)