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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.

The ATAC PAK CPK Reagent Kit and the ATAC 8000 Random Access Chemistry System are intended for use as a system for the quantitative determination of creatine kinase in serum and plasma. Creatine kinase results are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy. The ATAC PAK CPK Reagent determines creatine kinase through the enzymatic reduction of NAD to NADH. The resulting rate of increase in absorbance at approximately 340 nm is proportional to the creatine kinase activity in the sample. The ATAC PAK CPK Reagent Kit is substantially equivalent to the Beckman Creatine Kinase Reagent Kit, product no. 442635, marketed by Beckman Coulter, Inc. of Brea, CA.

The effectiveness of ATAC PAK CPK Reagent Kit and the ATAC 8000 Random Access Chemistry System is shown by the following studies.

The recovery of creatine kinase using the ATAC PAK CPK Reagent is linear from 4 to 1,600 U/L in the primary usable range and from 1,400 to 3,200 U/L in the hyperactive dilution range as shown by the recovery of linearity standards which span the respective ranges. The coefficient of determination (r^2) approaches 1.0 for both ranges, and the standard error of regression (sy.x) is less than 1.0% of the upper limit of the claimed range. Regression statistics, which compare standard recoveries to standard dilution factors in both ranges, are shown below.

Primary Usable Range
range = 0 - 1,635 U/L, $r^2 = 0.999$, sy.x = 13.8 U/L, df = 69

Hyperactive Usable Range
range = 1,317 - 3,212 U/L, $r^2 = 0.998$, sy.x = 28.3 U/L, df = 39

The lower limit of the linear range (4 U/L) is documented through the repetitive assay of a diluted serum control. The observed detection limit, calculated as two standard deviations of a 30 replicate within run precision study, is 1.2 U/L and is below the claimed limit.

Precision, using both the normal sample volume and the reduced sample volume with hyperactive dilution, is demonstrated by the replicate assay of commercially available serum controls. Precision statistics, calculated analogous to the method described in NCCLS Guideline EP3-T, are shown below.

Precision of Creatine Kinase Recoveries in U/L

			Within Run		Total	
Sample	n	mean	1SD	%CV	1SD	%CV
Serum 1	60	46	0.7	1.5%	1.4	3.0%
Serum 2	60	556	5.8	1.0%	16.2	2.9%
Serum 3	60	1177	11.9	1.0%	33.3	2.8%

Precision of Creatine Kinase Recoveries in U/L using Hyperactive Dilution

			Within Run		Total	
Sample	n	mean	1SD	%CV	1SD	%CV
Serum 1	70	2202	19	0.9%	45	2.1%
Serum 2	72	2636	29	1.1%	57	2.2%

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Mixed serum and plasma specimens, collected from adult patients, were assayed for creatine kinase at 37°C using the ATAC 8000 Random Access Chemistry System and another commercially available method. Results were compared by least squares linear regression and the following statistics were obtained.

ATAC 8000 = -6 U/L + 1.012 x Competitive Reagent
r = 0.999 n = 232 range = 4 - 1176 U/L

The 30 day on board reagent stability claim is documented through the assay of serum controls over the claimed period. In all cases, the total imprecision estimates of creatine kinase recoveries over the test period are less than the greater of 3 U/L or 3% for both the primary usable range and the extended hyperactive dilution range.

Wynn Stocking
Manager of Regulatory Affairs
Elan Diagnostics

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT - 3 2001

Mr. Wynn Stocking
Manager, Regulatory Affairs
Elan Diagnostics
1075 W. Lambert Road
Brea, CA 92821

Re: k012474
Trade/Device Name: ATAC PAK CPK Reagent
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: CGS
Dated: July 31, 2001
Received: August 2, 2001

Dear Mr. Stocking:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

K012474

510(k) Number (if known): K012474

Device Name: ATAC PAK CPK Reagent

Indications For Use:

The ATAC PAK CPK Reagent Kit and the ATAC 8000 Random Access Chemistry System are intended for use as a system for the quantitative determination of creatine kinase in serum and plasma. Creatine kinase measurements are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

This reagent is intended to be used by trained personnel in a professional setting and is not intended for home use.

Respectfully,

Wynn Stocking
Regulatory Affairs Manager
Elan Diagnostics

31 July, 2001

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012474

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)