JUL - 9 1999

K991789

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.

The ATAC-PAK Direct HDL Cholesterol Reagent Kit, the ATAC HDL-C Calibrator and the ATAC 8000 Random Access Chemistry System are used as a system for the quantitative analysis of high density lipoprotein cholesterol (HDL-C) in serum. HDL-cholesterol results are used in the diagnosis and treatment of lipid disorders, atherosclerosis and various liver and renal diseases, and as a tool to assess the risk of developing and managing the progression of cardiovascular disease.

The ATAC-PAK Direct HDL Cholesterol Reagent determines HDL-cholesterol through the enzymatic action of cholesterol esterase, cholesterol oxidase and peroxidase after the selective removal non-HDL sources of cholesterol. The resulting increase in absorbance at 578 nm is proportional to the HDL cholesterol concentration in the sample.

The ATAC-PAK Direct HDL Cholesterol Reagent Kit and ATAC HDL-C Calibrator are substantially equivalent to the Homogeneous Auto-Direct HDL-C Plus Reagent Kit, which is currently marketed by DMA, Inc.

The effectiveness of ATAC-PAK Direct HDL Cholesterol Reagent Kit and the ATAC HDL-C Calibrator used on the ATAC 8000 Random Access Chemistry System are shown by the following studies.

The recovery of HDL cholesterol using the ATAC-PAK Direct HDL Cholesterol Reagent is linear from 1 mg/dL to 150 mg/dL as shown by the recovery of linearity standards which span the claimed linear range. Regression statistics, comparing standard recoveries, which range from 0.6 to 155.5 mg/dL, to standard values are shown below.

(ATAC Recoveries) = 1.8 mg/dL + 0.981 x (Standard Value), $r^2 = 0.999$, $s_{y.x} = 1.77$ mg/dL, df = 8

Precision, demonstrated by replicate assay of commercially available control sera, is shown below.

Specimen	n	mean	within-run SD	total SD
Serum control 1	40	29.8 mg/dL	1.76 mg/dL	1.71 mg/dL
Serum control 2	40	45.1 mg/dL	2.26 mg/dL	2.23 mg/dL

One hundred and thirty eight serum specimens, collected from adult patients, were assayed for HDL cholesterol using the ATAC 8000 Random Access Chemistry System and another accepted clinical method. Results ranging from 17 to 99 mg/dL were compared by least squares linear regression and the following statistics were obtained.

y = 3.2 mg/dL + 0.938x r = 0.969
y = ATAC 8000 results x = accepted clinical method

The detection limit claim of 1 mg/dL is documented through the repetitive assay of a diluted HDL-C control. The observed detection limit, calculated as two standard deviations of a 22 replicate within run precision study, is 0.66 mg/dL and is below the claimed limit.

The 14 day on board reagent stability and calibration stability claims are documented through the assay of serum controls over the claimed periods. In all cases, the ranges of HDL-cholesterol recoveries over the test periods are less than 8 mg/dL.

Wynn Stocking

Wynn Stocking
Manager of Regulatory Affairs
Elan Diagnostics

Elan Diagnostics
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL - 9 1999

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

Re: K991789
Trade Name: ATAC-PAK Direct HDL Cholesterol Reagent
ATAC HDL-C Calibrator Kits
Regulatory Class: I reserved
Product Code: LBR
Dated: May 21, 1999
Received: May 25, 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): K991789

Device Name: ATAC-PAK Direct HDL Cholesterol Reagent and ATAC HDL-C Calibrator

Indications For Use:

The ATAC-PAK Direct HDL Cholesterol Reagent Kit, the ATAC HDL-C Calibrator and the ATAC 8000 Random Access Chemistry System are intended for use as a system for the quantitative determination of high density lipoprotein cholesterol in serum. HDL-cholesterol results are used in the diagnosis and treatment of lipid disorders, atherosclerosis and various liver and renal diseases, and as a tool to assess the risk of developing and managing the progression of cardiovascular disease.

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

21 May, 1999

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991789

(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)