K983914

DEC 22 1998

corgenix

SUMMARY OF 510(K) SAFETY AND EFFECTIVENESS
REAADS Monoclonal Free Protein S Antigen Test Kit
November 3, 1998

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 REAADS Monoclonal Free Protein S Antigen Test Kit is compared to a legally marketed predicate device and a substantial equivalence claim made. The predicate device is REAADS Protein S Antigen Test Kit (K972482/51) currently manufactured and marketed by Corgenix, Inc, Westminster, Colorado.

The REAADS Monoclonal Free Protein S Antigen Test Kit is an enzyme-linked immunosorbent assay (ELISA), utilizing the 96-microwell plate format, similar to the predicate device. A capture monoclonal antibody specific for human Free Protein S is coated to 96-microwell polystyrene plates. Diluted patient plasma is incubated in the wells, allowing any available Free Protein S to bind to the anti-human Free Protein S monoclonal antibody on the microwell surface. The plates are washed to remove unbound proteins or other plasma molecules. Bound Free Protein S is quantitated using horseradish peroxidase (HRP) conjugated anti-human Protein S detection polyclonal antibody. Following incubation, unbound conjugate is removed by washing. A chromogenic substrate of tetramethylbenzidine (TMB) and hydrogen peroxide (H_2O_2) is added to develop a colored reaction. The intensity of the color is measured in optical density (O.D.) units with a spectrophotometer at 450nm. Free Protein S relative percent concentrations in patient plasma are determined against a curve prepared from the reference plasma provided with the kit. Patient ODs are used to determine Free Protein S antigen levels in relative percent concentrations from a reference curve. The reference curve is produced by testing multiple dilutions of an assayed reference plasma supplied with the kit.

The intended use of the device is for the quantitative determination of Free Protein S Antigen in human citrated plasma (as a percent of normal concentration) by enzyme-linked immunosorbant assay (ELISA). Plasma levels of Free Protein S may be used in conjunction with results in other assays as an aid in diagnosing congenital or acquired Protein S deficiencies associated with thrombotic disease. A decreased Protein S activity in plasma may be the result of low concentrations or abnormal function of the Protein S molecule. Using an ELISA with a monoclonal antibody allows the direct measurement Free Protein S without PEG precipitation. Measurement of plasma levels of both Total and Free Protein S are useful to determine the type of defect in patients with Protein S deficiency.

Test results for clinical samples demonstrate that the REAADS Monoclonal Free Protein S Antigen Test Kit and REAADS Protein S Antigen Test Kit (PEG Method) are equivalent. The coefficient of correlation (r) for all plasma samples, including the suspected deficient samples was 0.956, with a P-value of 0.109 (by single factor ANOVA), indicating the results by the two methods are statistically similar. Although differences between the assays are observed, in general, the performance characteristics are comparable. The differences may be attributed to the improved specificity of the REAADS Monoclonal Test Kit compared to the REAADS PEG Test Kit. The clinical studies performed demonstrate that the REAADS Monoclonal Free Protein S Antigen Test Kit is safe and effective.

Nanci Dexter — 11-3-98

Nanci Dexter
Director, Quality Assurance and Regulatory Affairs

Date

12061 TEJON STREET • WESTMINSTER, CO • 80234 U.S.A.
PHONE: 303.457.4345 FAX: 303.457.4519 www.corgenix.com

In response to the requirements by the SMDA of 1990, enclosed on a separate letterhead page is the Summary of 510(k) Safety and Effectiveness information upon which the substantial equivalence determination is based.

Please contact me at the address, phone, or fax number shown if you have questions or comments about this submission.

Sincerely,

Nanci Dexter
Director, Quality Assurance and Regulatory Affairs

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
[As required by 21 CFR 807.87(j)]

I certify that, in my capacity as Director of Quality Assurance and Regulatory Affairs for Corgenix, Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Nanci Dexter

11-3-98
Date

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 22 1998

Ms. Nanci Dexter
Director of Quality and Regulatory Affairs
CORGENIX, INC.
12061 Tejon St.
Westminster, CO 80234

Re: K983914
Trade Name: REAADS Monoclonal Free Protein S Antigen Test Kit
Regulatory Class: II
Product Code: GGP
Dated: November 3, 1998
Received: November 4, 1998

Dear Ms. Dexter:

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.

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

Indications for Use Statement

510(k) Number: K983914

Device Name: REAADS Monoclonal Free Protein S Antigen Test Kit

Indications for Use:

The REAADS Monoclonal Free Protein S Antigen Test Kit is an in vitro diagnostic assay for the quantitative determination of Free Protein S levels in human citrated plasma (as a percent of normal concentration) by enzyme-linked immunosorbant assay (ELISA).

The REAADS Monoclonal Free Protein S Antigen Test Kit is intended to be used by clinical (hospital and reference) laboratories.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maxim

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983914

Presumption ✓