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K982391

corgenix CORGENIX, INC.

SUMMARY OF 510(K) SAFETY AND EFFECTIVENESS

REAADS IgG anti-B2GPI Test Kit

July 8, 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 IgG anti-B2GPI Test Kit is compared to a legally marketed predicate device and a substantial equivalence claim made. The predicate device is QUANTA Lite IgG anti B2GPI ELISA (K970551) currently manufactured and marketed by INOVA Diagnostics, Inc., San Diego, California.

The REAADS IgG anti-B2GPI Test Kit is an enzyme-linked immunosorbent assay (ELISA), utilizing the 96-microwell plate format, similar to the predicate device. Diluted serum samples, calibrator sera, and controls are incubated in microwells coated with purified human Beta-2 Glycoprotein I. Incubation allows the anti-B2GPI antibodies present in the samples to react with the immobilized antigen. After the removal of unbound serum proteins by washing, antibodies specific for human IgG, labeled with horseradish peroxidase (HRP), are added forming complexes with the B2GPI bound antibodies. Following another washing step, the bound enzyme-antibody conjugate is assayed by the addition of a single solution containing tetramethlybenzidine (TMB) and hydrogen peroxide (H_2O_2) as the chromogenic substrate. The intensity of the color generated is proportional to the serum concentration of anti-B2GPI antibodies. Optical density is read spectrophotometrically at 450nm. The total incubation time (at room temperature) of the assay is 40 minutes. The assay makes use of a single point calibrator to measure the amount of IgG anti-B2GPI antibodies in patient samples.

The intended use of the device is for the detection and semi-quantitation of IgG anti-B2GPI antibodies in human serum as an aid for assessing the risk of thrombosis in individuals with systemic lupus erythematosus (SLE) and lupus-like disorders (antiphospholipid syndrome). Most autoimmune anti-phospholipid antibodies require a serum cofactor (B2GPI) for optimal binding. It has been shown that many anti-phospholipid antibodies may react to a neoepitope formed on the B2GPI molecule by the interaction between the phospholipid and B2GPI. In addition, it has been reported that anti-B2GPI antibodies are more specific for thrombosis than antibodies detected by classic antiphospholipid ELISAs. Testing for anti-B2GPI antibodies in the clinical laboratory by ELISA is becoming increasingly valuable and provides additional clinically relevant results to assess patients for the antiphospholipid syndrome and/or the risk of thrombosis.

Performance indicates that REAADS anti-Beta-2 Glycoprotein I and the QUANTA Lite IgG anti B2GPI ELISA are equivalent. In-house studies indicate a clinical specificity of 100% for IgG anti-B2GPI antibodies and a clinical sensitivity of 32% for unselected SLE patients. The coefficient of correlation for individual values in unselected SLE patients showed a good correlation of 0.834 with a P-value of 0.05 (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. These results are also in compliance with those in published literature for antiphospholipid syndrome detection. The clinical studies performed demonstrate that the REAADS IgG anti-B2GPI Test Kit is safe and effective.

Nanci Dexter

07/08/98

Nanci Dexter
Director, Quality Assurance and Regulatory Affairs

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 7 1998

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

Re: K982391
Trade Name: REAADS IgG Anti-B2GPI Test Kit
Regulatory Class: II
Product Code: MSV
Dated: November 16, 1998
Received: November 18, 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: K982391

Device Name:

Indications for Use:

The REAADS IgG anti-B2GPI Test Kit is an in vitro diagnostic assay for the detection and semi-quantitation of IgG anti-B2GPI antibodies in human serum as an aid for assessing the risk of thrombosis in individuals with systemic lupus erythematosus (SLE) and lupus-like disorders (antiphospholipid syndrome).

The REAADS IgG anti-B2GPI 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)

Prescription Use ✓

Peter E. Madsen

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K982391