DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Nanci Dexter
Director of Quality and Regulatory Affairs
Corgenix, Inc.
12061 Tejon Street
Westminster, Colorado 80234

JUL 0 7 2003

Re: k031208
Trade/Device Name: REAADS IgM anti-B2GPI Test Kit
REAADS IgA anti-B2GPI Test Kit
REAADS IgG anti-B2GPI Test Kit
REAADS IgG Anti-Prothrombin Semi-Quantitative Test Kit
REAADS IgM Anti-Prothrombin Semi-Quantitative Test Kit
Regulation Number: 21 CFR § 866.5660
Regulation Name: Multiple Autoantibodies Immunological Test System
Regulatory Class: II
Product Code: MSV, DHC
Dated: June 20, 2003
Received: June 25, 2003

Dear Ms. Dexter:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K031208

Device Name: REAADS IgM anti-B2GPI Test Kit
Indications for Use:

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

The REAADS IgM anti-B2GPI Test Kit is intended to be used by clinical (hospital and reference) laboratories.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

J P Reeves for J. Bautista
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031208

Prescription Use ✓

Indications for Use Statement

510(k) Number: K031208

Device Name: REAADS IgA anti-B2GI Test Kit
Indications for Use:

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

The REAADS IgA 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)

H.Reeves for J. Bautista
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031208

Prescription Use ✓

Indications for Use Statement

510(k) Number: K031208

Device Name: REAADS IgG anti-B2GI Test Kit
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 or plasma 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.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

J P Reeves for J. Bautista
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031208

Prescription Use ✓

Indications for Use Statement

510(k) Number: K031208

Device Name: REAADS IgG Anti-Prothrombin Semi-Quantitative Test Kit

Indications for Use:

The REAADS IgG Anti-Prothrombin Semi-Quantitative Test Kit is an in vitro diagnostic assay for the detection and semi-quantitation of IgG anti-prothrombin (aPT) antibodies in individuals with systemic lupus erythematosus (SLE) and lupus-like disorders (antiphospholipid syndrome).

The REAADS IgG Anti-Prothrombin Semi-Quantitative Test Kit is intended to be used by clinical (hospital and reference) laboratories.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

J P Rawls for J. Bautista

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031208

Prescription Use ✓

Indications for Use Statement

510(k) Number: K031208

Device Name: REAADS IgM Anti-Prothrombin Semi-Quantitative Test Kit

Indications for Use:

The REAADS IgM Anti-Prothrombin Semi-Quantitative Test Kit is an in vitro diagnostic assay for the detection and semi-quantitation of IgM anti-prothrombin (aPT) antibodies in individuals with systemic lupus erythematosus (SLE) and lupus-like disorders (antiphospholipid syndrome).

The REAADS IgM Anti-Prothrombin Semi-Quantitative 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)

J P Reeves for J. Bautista

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031208

Prescription Use ✓