



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

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

OCT 20 2003

Re: k032868

Device Name: REAADS II anti-Cardiolipin IgG Semi-quantitative Test Kit  
REAADS II anti-Cardiolipin IgM Semi-quantitative Test Kit  
REAADS II anti-Cardiolipin IgA Semi-quantitative Test Kit  
REAADS II anti-Phosphatidylserine IgG Semiquantitative Test Kit  
REAADS II anti-Phosphatidylserine IgM Semiquantitative Test Kit  
REAADS II anti-Phosphatidylserine IgA Semiquantitative Test Kit  
REAADS II anti-Beta 2 Glycoprotein I IgG Semi-Quantitative Test Kit  
REAADS II anti-Beta 2 Glycoprotein I IgM Semi-Quantitative Test Kit  
REAADS II anti-Beta 2 Glycoprotein I IgA Semi-Quantitative Test Kit  
REAADS II anti-Prothrombin IgG Semi-Quantitative Test Kit  
REAADS II anti-Prothrombin IgM Semi-Quantitative Test Kit

Regulation Number: 21 CFR § 866.5660

Regulation Name: Multiple Autoantibodies Immunological Test System

Regulatory Class: II

Product Code: MID, MSV, DHC

Dated: September 12, 2003

Received: September 15, 2003

Dear Ms. Dexter:

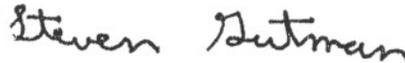
This letter corrects our substantially equivalent letter of October 14, 2003 regarding the incorrect company name. We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications 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 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: K032868

Device Name: REAADS® II Anti-Cardiolipin IgM Semi-Quantitative Test Kit

### Indications for Use:

The REAADS® II Anti-Cardiolipin IgM Semi-Quantitative Test Kit is an enzyme-linked immunosorbent assay (ELISA) for the semi-quantitative determination of anti-cardiolipin IgM antibodies in human serum or plasma.

For the detection and semi-quantitation of anti-cardiolipin antibodies in individuals with systemic lupus erythematosus (SLE) and lupus-like disorders (anti-phospholipid syndrome).

The REAADS® II Anti-Cardiolipin IgM Semi-Quantitative Test Kit is intended to be used by clinical (hospital and reference) laboratories.

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IF NECESSARY)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

J. P. Rawls for T. J. O'Leary  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K032868

Prescription Use ✓

## Indications for Use Statement

510(k) Number: K032868

Device Name: REAADS® II Anti-Cardiolipin IgG Semi-Quantitative Test Kit

### Indications for Use:

The REAADS® II Anti-Cardiolipin IgG Semi-Quantitative Test Kit is an enzyme-linked immunosorbent assay (ELISA) for the semi-quantitative determination of anti-cardiolipin IgG antibodies in human serum or plasma.

For the detection and semi-quantitation of anti-cardiolipin antibodies in individuals with systemic lupus erythematosus (SLE) and lupus-like disorders (anti-phospholipid syndrome).

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

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Evaluation and Safety

510(k) K032868

Prescription Use ✓

## Indications for Use Statement

510(k) Number: K032868

Device Name: REAADS® II Anti-Cardiolipin IgA Semi-Quantitative Test Kit

### Indications for Use:

The REAADS® II Anti-Cardiolipin IgA Semi-Quantitative Test Kit is an enzyme-linked immunosorbent assay (ELISA) for the semi-quantitative determination of anti-cardiolipin IgA antibodies in human serum or plasma.

For the detection and semi-quantitation of anti-cardiolipin antibodies in individuals with systemic lupus erythematosus (SLE) and lupus-like disorders (anti-phospholipid syndrome).

The REAADS® II Anti-Cardiolipin IgA Semi-Quantitative Test Kit is intended to be used by clinical (hospital and reference) laboratories.

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510(k) K032868

Prescription Use

## Indications for Use Statement

510(k) Number: K032868

Device Name: REAADS® II Anti-Phosphatidylserine IgG Semi-Quantitative Test Kit

### Indications for Use:

The REAADS® II Anti-Phosphatidylserine IgG Semi-Quantitative Test Kit is an enzyme-linked immunosorbent assay (ELISA) for the semi-quantitative determination of anti-phosphatidylserine IgG antibodies in human serum or citrated plasma (3.2% sodium citrate).

Detection and semi-quantitation of anti-phosphatidylserine antibodies in individuals with systemic lupus erythematosus (SLE) and lupus-like disorders (anti-phospholipid syndrome).

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

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Prescription Use

## Indications for Use Statement

510(k) Number: K032868

Device Name: REAADS® II Anti-Phosphatidylserine IgM Semi-Quantitative Test Kit

### Indications for Use:

The REAADS® II Anti-Phosphatidylserine IgM Semi-Quantitative Test Kit is an enzyme-linked immunosorbent assay (ELISA) for the semi-quantitative determination of anti-phosphatidylserine IgM antibodies in human serum or citrated plasma (3.2% sodium citrate).

Detection and semi-quantitation of anti-phosphatidylserine antibodies in individuals with systemic lupus erythematosus (SLE) and lupus-like disorders (anti-phospholipid syndrome).

The REAADS® II Anti-Phosphatidylserine IgM Semi-Quantitative Test Kit is intended to be used by clinical (hospital and reference) laboratories.

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Approved for T.J. O'Leary  
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Prescription Use

## Indications for Use Statement

510(k) Number: K032868

Device Name: REAADS® II Anti-Phosphatidylserine IgA Semi-Quantitative Test Kit

### Indications for Use:

The REAADS® II Anti-Phosphatidylserine IgA Semi-Quantitative Test Kit is an enzyme-linked immunosorbent assay (ELISA) for the semi-quantitative determination of anti-phosphatidylserine (aPS) IgA antibodies in human serum and citrated plasma (3.2% sodium citrate).

Detection and semi-quantitation of anti-phosphatidylserine antibodies in individuals with systemic lupus erythematosus (SLE) and lupus-like disorders (anti-phospholipid syndrome).

The REAADS® II Anti-Phosphatidylserine IgA Semi-Quantitative Test Kit is intended to be used by clinical (hospital and reference) laboratories.

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510(k) K032868

Prescription Use

## Indications for Use Statement

510(k) Number: K032868

Device Name: REAADS® II Anti-Beta 2 Glycoprotein I IgG Semi-Quantitative Test Kit

### Indications for Use:

The REAADS® II Anti-Beta 2 Glycoprotein I IgG Semi-Quantitative Test Kit is an enzyme-linked immunosorbent assay (ELISA) for the semi-quantitative determination of anti-Beta 2 Glycoprotein I ( $\beta$ 2GPI) IgG antibodies in human serum or citrated plasma (3.2% sodium citrate).

For the detection and semi-quantitation of anti- $\beta$ 2GPI IgG antibodies in individuals with systemic lupus erythematosus (SLE) and lupus-like disorders (anti-phospholipid syndrome).

The REAADS® II Anti-Beta 2 Glycoprotein I IgG Semi-Quantitative Test Kit is intended to be used by clinical (hospital and reference) laboratories.

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Prescription Use

## Indications for Use Statement

510(k) Number: K032868

Device Name: REAADS® II Anti-Beta 2 Glycoprotein I IgM Semi-Quantitative Test Kit

### Indications for Use:

The REAADS® II Anti-Beta 2 Glycoprotein I IgM Semi-Quantitative Test Kit is an enzyme-linked immunosorbent assay (ELISA) for the semi-quantitative determination of anti-Beta 2 Glycoprotein I ( $\beta$ 2GPI) IgM antibodies in human serum or citrated plasma (3.2% sodium citrate).

For the detection and semi-quantitation of anti- $\beta$ 2GPI IgM antibodies in individuals with systemic lupus erythematosus (SLE) and lupus-like disorders (anti-phospholipid syndrome).

The REAADS® II Anti-Beta 2 Glycoprotein I IgM Semi-Quantitative Test Kit is intended to be used by clinical (hospital and reference) laboratories.

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Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K032868

Prescription Use

## Indications for Use Statement

510(k) Number: K032868

Device Name: REAADS® II Anti-Beta 2 Glycoprotein I IgA Semi-Quantitative Test Kit

### Indications for Use:

The REAADS® II Anti-Beta 2 Glycoprotein I IgA Semi-Quantitative Test Kit is an enzyme-linked immunosorbent assay (ELISA) for the semi-quantitative determination of anti-Beta 2 Glycoprotein I ( $\beta$ 2GPI) IgA antibodies in human serum or citrated plasma (3.2% sodium citrate).

For the detection and semi-quantitation of anti- $\beta$ 2GPI IgA antibodies in individuals with systemic lupus erythematosus (SLE) and lupus-like disorders (anti-phospholipid syndrome).

The REAADS® II Anti-Beta 2 Glycoprotein I IgA Semi-Quantitative Test Kit is intended to be used by clinical (hospital and reference) laboratories.

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510(k) K032868

Prescription Use

## Indications for Use Statement

510(k) Number: K032868

Device Name: REAADS<sup>®</sup> II Anti-Prothrombin IgG Semi-Quantitative Test Kit

### Indications for Use:

The REAADS<sup>®</sup> II Anti-Prothrombin IgG Semi-Quantitative Test Kit is an enzyme-linked immunosorbent assay (ELISA) for the semi-quantitative determination of anti-prothrombin (aPT) IgG antibodies in human serum or citrated plasma (3.2% sodium citrate).

For the detection and semi-quantitation of anti-prothrombin (aPT) IgG antibodies in individuals with systemic lupus erythematosus (SLE) and lupus-like disorders (e.g., antiphospholipid syndrome).

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

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Prescription Use

## Indications for Use Statement

510(k) Number: K032868

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

### Indications for Use:

The REAADS® II Anti-Prothrombin IgM Semi-Quantitative Test Kit is an enzyme-linked immunosorbent assay (ELISA) for the semi-quantitative determination of anti-prothrombin (aPT) IgM antibodies in human serum or citrated plasma (3.2% sodium citrate).

For the detection and semi-quantitation of anti-prothrombin (aPT) IgM antibodies in individuals with systemic lupus erythematosus (SLE) and lupus-like disorders (e.g., antiphospholipid syndrome).

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

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