RhiGene Inc.
an MBL Company

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K042680

NOV 19 2004

**SUMMARY OF 510(K) SAFETY AND EFFECTIVENESS**
**HEP-ANAN Test System**
September 10, 2004

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 HEP-ANA Test system is compared to a legally marketed predicate device and a substantial equivalence claim made. The predicate device is RhiGene Titer-Fluor ANA Test System (manufactured by BION ENTERPRISES, Des Plaines, IL, K872845), currently marketed by RhiGene, Inc. Des Plaines, IL.

The RhiGene HEP-ANA Test System is an indirect fluorescent antibody assay utilizing HEp-2 tissue culture cells as a substrate, similar to the predicate device. Diluted serum samples and controls are incubated on substrate slides coated with HEp-2 (human epithelial) cells. Incubation allows the anti-nuclear antibodies (ANA) present in the samples to react with the antigen. After the removal of unbound serum proteins by washing, antibodies specific for human immunoglobulins, labeled with fluorescein isothiocyanate (FITC), are added forming complexes with the nuclear bound antibodies. Following another washing step, coverslips are mounted and then the slides are examined with a fluorescence microscope. The total incubation time (at room temperature in a moist chamber) of the assay is 40 minutes.

The intended use of the device is a qualitative and/or semi-quantitative indirect fluorescent antibody assay for the determination of antinuclear antibodies in human serum. The HEP-ANA Test System is intended for *in vitro* diagnostic use as an aid in the determination of certain autoimmune diseases.

Performance indicates that HEP-ANA Test system and the RhiGene Titer-Fluor ANA Test System are equivalent. In-house studies indicate a clinical specificity of 82% and 78% for ANA in a healthy donor serum population respectively. Additional studies resulted a sensitivity of 75% with an autoimmune diseases population on both assay. In general, the performance characteristics are comparable between the two methods. These results are also in compliance with those in published literature for ANA detection. The clinical studies performed demonstrate that the HEP-ANA test system is safe and effective.

Yusuke Kobe

9/15/2004
Date

Yusuke Kobe
Vice President, Sales and Marketing Department

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Corgenix, Inc.
c/o Mr. Yusuke Kobe
Vice President
Rhigene, Inc.
455 State Street
Des Plaines, IL 60016

NOV 19 2004

Re: k042680
Trade/Device Name: RhiGene Hep-ANA Test System
Regulation Number: 21 CFR 866.5100
Regulation Name: Antinuclear Antibody, Immunological Test System
Regulatory Class: Class II
Product Code: DHN
Dated: September 14, 2004
Received: September 29, 2004

Dear Mr Kobe:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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), please contact the Office of Compliance at (240) 276-3084. 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,

Robert L. Becker, Jr., M.D., PhD
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K 042680

Device Name: RhiGene HEP-ANA Test System

Indications For Use:

The HEP-ANA Test System is an indirect fluorescent antibody assay utilizing HEp-2 tissue culture cells as a substrate for the qualitative and/or semi-quantitative determination of antinuclear antibodies in human serum. The HEP-ANA Test System is intended for use as an aid in the diagnosis of certain autoimmune diseases.

The HEP-ANA Test System is intended to be used by clinical (hospital and reference) laboratories.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Maria Chan

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K042680