K040200

MAR - 4 2004

RhiGene

SUMMARY OF 510(K) SAFETY AND EFFECTIVENESS
MESACUP-2 Test CENP-B
January 27, 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 MESACUP-2 Test CENP-B is compared to a legally marketed predicate device and a substantial equivalence claim made. The predicate device is Quanta Lite Centromere ELISA (K926562) currently manufactured and marketed by Inova Diagnostics, Inc., 10180 Scripps Ranch Boulevard, San Diego, CA 92131.

The MESACUP-2 Test CENP-B 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 CENP-B antigen. Incubation allows the anti-CENP-B antibodies present in the samples to react with the immobilized antigen. After the removal of unbound serum proteins by washing, antibodies specific for human immunoglobulins (IgG, IgM and IgA), labeled with horseradish peroxidase (HRP), are added forming complexes with the CENP-B 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-Jo-1 antibodies. Optical density is read spectrophotometrically at 450nm. The total incubation time (at room temperature) of the assay is 150 minutes. The assay makes use of two calibrators to measure the amount of anti-CENP-B antibody in patient samples.

The intended use of the device is a semi-quantitative enzyme-linked immunosorbent assay (ELISA) for the detection of anti-CENP-B antibodies in human serum. The MESACUP-2 Test CENP-B is intended for in vitro diagnostic use as an aid in the determination of CREST syndrome and related connective tissue diseases..

Performance indicates that MESACUP-2 Test CENP-B and the Quanta Lite Centromere ELISA are equivalent. In-house studies indicate a clinical specificity of 95% and 100% for anti-CENP-B antibodies in a healthy donor serum population respectively. Additional studies resulted a sensitivity of 90% and 95% with a CREST Syndrome population on both assay respectively for anti-CENP-B antibodies previously also found positive by double immunodiffusion (DID). In general, the performance characteristics are comparable between the two methods (95% relative agreement).

Yusuke Kobe
Vice President, Sales and Marketing Department

1/28/2004
Date

455 State St. Ste 104 Des Plaines, IL 60016 Tel : (847) 375-9091 Fax: (847) 375-9093

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR - 4 2004

Mr. Yusuke Kobe
VP, Sales and Marketing Department
Rhigene, Inc
455 State Street – Suite 104
Des Plaines, IL 60016

Re: k040200
Trade/Device Name: MESACUP-2 Test CENP-B
Regulation Number: 21 CFR 866.5100
Regulation Name: Antinuclear antibody immunological test system
Regulatory Class: Class II
Product Code: LJM
Dated: February 24, 2004
Received: February 25, 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.

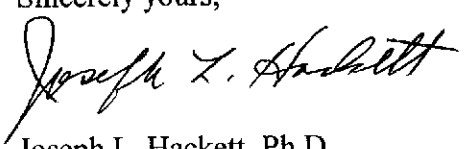
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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,



Joseph L. Hackett, Ph.D.
Acting Director
Division of Immunology and Hematology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K040200

Device Name: MESACUP-2 Test CENP-B

Indications for Use:

The MESACUP-2 Test CENP-B is a semi-quantitative enzyme-linked immunosorbent assay (ELISA) for the detection of anti-CENP-B antibodies in human serum. The MESACUP-2 Test CENP-B is intended for in vitro diagnostic use as an aid in the diagnosis of CREST syndrome and related connective tissue diseases.

The MESACUP-2 Test CENP-B 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 ✓ **OR** **Over-The-Couter Use** ____
(per 21 CFR 801.109)

Optional Format 1-2-96)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) 040200