JUN 19 2006

K 060431

510(k) Summary

MBL INTERNATIONAL CORPORATION
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Woburn, Ma 01801
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Contact: Yusuke Kobe, Vice President, Sales and Marketing
Prepared February 14, 2006

1. **Identification of the Device**:
   Proprietary-Trade Name: Anti RNA Polymerase III ELISA Kit
   Classification Name/Product Codes: LJM
   Common/Usual Name: ELISA In-Vitro Diagnostic Kit

2. **Equivalent legally marketed devices**: K040200 MESACUP-2 TEST CENP-B, MBL International (formerly Rhigene), and K972145, HEP-2000 FLUORESCENT ANA-RO TEST SYSTEM, Immuno Concepts.

3. **Indications for Use (intended use)** : The anti-RNA Polymerase III ELISA Kit is a semi-quantitative, enzyme-linked immunosorbent assay (ELISA) for the detection of anti-RNA Polymerase III antibodies in human serum. The test result is used as an aid in the diagnosis of Systemic Sclerosis (SSc) in conjunction with the clinical and other laboratory findings. The anti-RNA Polymerase III ELISA Kit is intended for in-vitro diagnostic use.

4. **Description of the Device**: This device is an aid to the diagnosis of SSc. Systemic sclerosis (SSc) is an autoimmune disease characterized by microvascular damage and fibrosis of the skin and internal organs. RNA polymerase(RNAP) I, II and III are major targets of autoantibody responses in SSc patients. Each RNAP catalyzes transcription of unique sets of genes: RNAP I transcribes ribosomal RNA genes, RNAP II transcribes all protein coding genes and several small nuclear RNA genes, and RNAP III transcribes genes that produce small stable RNAs including 5S and transfer RNAs. Anti-RNAP I and anti-RNAP III antibodies are almost always present together (anti-RNAP I/III), and some sera contain anti-RNAP II antibody as well. Anti-RNAP I/III antibodies are the most common SSc related antibodies in white North American patients with SSc and is associated with diffuse cutaneous involvement, a high frequency of "renal crisis", and high mortality. In addition, it has been shown that some SSc sera contain autoantibodies recognizing RNAP II but not RNAP I or III. Antibodies to RNAP II are also present in sera from some patients with systemic lupus erythematosus (SLE) or overlap syndrome. PRINCIPLE: The anti-RNA Polymerase III ELISA Kit measures anti-RNAP III antibodies present in the serum by ELISA. Diluted Calibrators and patient serum are added to microwell coated with RNAP III antigens, allowing anti-RNAP III antibodies to react with the immobilized antigen (Sample incubation). After washing to remove any unbound serum proteins, horseradish peroxidase conjugated anti human IgG is added and incubated (Conjugate incubation). Following another washing step, the peroxidase substrate is added and incubated for an additional period of time (Substrate incubation). Acid solution is then added to each well to terminate the enzyme reaction and to stabilize the color development. The assay can be quantified by measuring the reaction photometrically and plotting the results.

5. **Safety and Effectiveness, comparison to predicate device.** The results of clinical and non-clinical testing indicates that the new device is as safe and effective as the predicate devices and methods.

6. **Substantial Equivalence Chart**

Characteristic	K040200 MESACUP-2 TEST CENP-B, MBL International (formerly Rhigene)	K972145, HEP-2000 FLUORESCENT ANA-RO TEST SYSTEM, Immuno Concepts	Anti RNA Polymerase III ELISA Kit
Indications	The MESACUP-2 Test CENP-B is a semi-quantitative enzyme-linked immunosorbent assay (ELBA) for the detection of anti-CENP-B antibodies inhuman 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.	This is an indirect fluorescent antibody test for the semi-quantitative detection of antinuclear antibodies in human serum, with specific identification of autoantibodies to the SS-A/Ro antigen. This test system is to be used as an aid in the detection of antibodies associated with system rheumatic disease	The anti-RNA Polymerase III ELISA Kit is a semi-quantitative, enzyme-linked immunosorbent assay (ELISA) for the detection of anti-RNA Polymerase III antibodies in human serum. The anti-RNA Polymerase III ELISA Kit is intended for in-vitro diagnostic use
Technology	ELISA	Indirect fluorescent	ELISA
Detect what?	ANA	ANA	ANA
Disease	Crest syndrome	Multiple anti-immune diseases, systemic rheumatic disease	Systemic sclerosis (SSc)
Test fluid	Serum	Serum	Serum
USE	IVD	IVD	IVD

7. **Conclusion**

After analyzing clinical and non-clinical testing data, it is the conclusion of MBL INTERNATIONAL CORPORATION that the Anti RNA Polymerase III ELISA Kit is as safe and effective as the predicate devices, thus rendering it substantially equivalent to the predicate device. Performance characteristics were established in a clinical trial via comparison with a research method, Immunoprecipitation, AND K972145, HEP-2000 FLUORESCENT ANA-RO TEST SYSTEM.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 19 2006

MBL International Corporation
c/o Mr. Daniel Kamm
Kamm & Associates
P.O. Box 7007
Deerfield, IL 60015

Re: k060431
Trade/Device Name: MBL Anti-RNA Polymerase III ELISA Kit
Regulation Number: 21 CFR 866.5100
Regulation Name: Antinuclear antibody immunological system
Regulatory Class: Class II
Product Code: NYO
Dated: February 16, 2006
Received: February 27, 2006

Dear Mr. Kamm:

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.

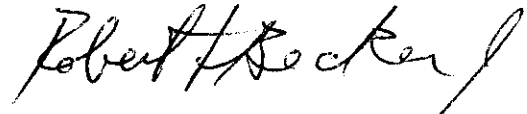
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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), please contact the Office of Compliance at (240) 276-0484. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Robert L. Becker, Jr., M.D., Ph.D.
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): **K060431**

Device Name: **Anti RNA Polymerase III ELISA Kit**

Indications For Use:

The anti-RNA Polymerase III ELISA Kit is a semi-quantitative, enzyme-linked immunosorbent assay (ELISA) for the detection of anti-RNA Polymerase III antibodies in human serum. The test result is used as an aid in the diagnosis of Systemic Sclerosis (SSc) in conjunction with the clinical and other laboratory findings. The anti-RNA Polymerase III ELISA Kit is intended for in-vitro diagnostic use.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Maria M. Chan

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