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9. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safety Medical Devices Act of 1990 (SMDA 1990) and 21 CFR Part 807.92.

Assigned 510(k) Number: K993589

Date of Summary Preparation: October 12 , 1999

Distributor:
Pharmacia & Upjohn
Diagnostics Division, US Operation
7425-248-1
7000 Portage Road
Kalamazoo, MI 49001

Manufacturer:
Pharmacia & Upjohn Diagnostics GmbH & Co. KG
Munzingerstrasse 7
D-79111 Freiburg, Germany

Company Contact Person:
Karen E.Matis
Manager, Regulatory Affairs and Quality Management
Diagnostics Division
US Operation
7000 Portage Road
7425-248-01
Kalamazoo, MI 49001
(614) 794-3324 (Phone)
(614) 794-0266 (Fax)

Device Name: Varelisa® RNPAntibodies

Common Name: Antinuclear antibody immunological test

Classification:

Product Name	Product Code	Class	CFR
Varelisa® RNP Antibodies	82LJM	II	866.5510

Substantial Equivalence to:

Synelisa™ U1-snRNP Antibodies

Intended Use Statement:

The Varelisa® RNP Antibodies EIA kit is designed for the semiquantitative and qualitative determination of RNP antibodies in serum or plasma to aid in the diagnosis of Systemic Lupus Erythematosus (SLE) and Mixed Connective Tissue Disease (MCTD). _

General Description of the Device

The Varelisa RNP Antibodies is an enzyme immunoassay for the semiquantitative and qualitative determination of RNP antibodies in serum or plasma.

The determination of RNP antibodies is of central importance for the clinical diagnosis rheumatic autoimmune diseases. The presence of RNP antibodies suggests the possibility of Systemic Lupus Erythematosus (SLE) and Mixed Connective Tissue Diseases (MCTD).

Varelisa® RNP Antibodies Test Principle

The Varelisa RNP Antibodies is an indirect noncompetitive enzyme immunoassay. The wells of a microplate are coated with human recombinant RNP (68 kDa, A, C) antigens. Antibodies specific for RNP present in a patient sample bind to this antigen.

In a second step an enzyme labeled second antibody (Conjugate) binds to the antigen-antibody complex which leads to the formation of an enzyme labeled antigen-antibody sandwich complex.

The enzyme labeled antigen-antibody complex converts the added substrate to form a colored solution. The rate of color formation from the chromogen is a function of the amount of Conjugate complexed with the bound antibody and thus is proportional to the initial concentration of the respective antibodies in the patient sample.

Device Comparison:

Synelisa® U1-snRNP (68 kDa) Antibodies (the predicate device) and Varelisa® RNP Antibodies Assay (the new device) are both indirect noncompetitive enzyme immuno-assays for the determination of RNP antibodies in serum or plasma to aid in the diagnosis of Systemic Lupus Erythematosus (SLE) and Mixed Connective Tissue Disease (MCTD).

The essential difference between the two assays is the inclusion of the recombinant RNP A and RNP C proteins in addition to the RNP (68 kDa) protein in the antigen mixture of the new device. The new device now includes the three major antigens of the U1-RNP complex.

Laboratory Equivalence

70 samples including 20 apparently healthy blood donors were tested. Excluding 8 samples for which a different result was expected, the overall agreement was 92%. 5 of the omitted samples were found to be equivocal in Varelisa RNP Antibodies (for Synelisa U1-snRNP (68kDa) Antibodies, no equivocal range is defined). The other 3 omitted samples were shown to contain antibodies directed against the RNP proteins A and C. Since the Synelisa U1-snRNP (68kDa) does not contain RNP A and C, antibodies directed against these antigens can only be detected by the Varelisa RNP Antibodies assay.

The blood donor samples were all found negative in both assays.

These results demonstrate an excellent agreement between both assays.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 26 1999

Ms. Karen E. Matis
Manager, Regulatory Affairs and
Quality Management
Pharmacia & Upjohn
7000 Portage Road
Kalamazoo, Michigan 49001-0199

Re: K993589
Trade Name: Varelisa® RNP Antibodies
Regulatory Class: II
Product Code: LKO
Dated: October 20, 1999
Received: October 22, 1999

Dear Ms. Matis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Varelisa® RNP Antibodies
510(k) Submission
Section 1. Indications For Use Statement

510(k) Number: K993589

Device Name: **Varelisa® RNP Antibodies**

The Varelisa RNP Antibodies EIA kit is designed for the semiquantitative and qualitative determination of RNP antibodies in serum or plasma to aid in the diagnosis of Systemic Lupus Erythematosus (SLE) and Mixed Connective Tissue Disease (MCTD).

Peter E. Maxfield
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993589

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)