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: K993108

Date of Summary Preparation: September 8, 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:
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Diagnostics Division
US Operation
7000 Portage Road
7425-248-01
Kalamazoo, MI 49001
(614) 794-3324 (Phone)
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Device Name: Varelisa® ReCombi ANA Screen

Common Name: Antinuclear antibody immunological test

Classification:

Product Name	Product Code	Class	CFR
Varelisa® ReCombi ANA Screen	82LJM	II	866.5100

00 00078

Substantial Equivalence to:

Varelisa® ANA-8-ScreenAssay

Intended Use Statement:

The Varelisa® ReCombi ANA Screen EIA kit is designed for the qualitative determination of eight antinuclear antibodies in human serum or plasma to aid in the diagnosis of systemic rheumatic diseases such as SLE (Systemic Lupus Erythematosus), Scleroderma (Progressive Systemic Sclerosis), MCTD (Mixed Connective Tissue Disease), SS (Sjögren's Syndrome) and Polymyositis/ Dermatomyositis. The Varelisa ReCombi ANA Screen detects antibodies against dsDNA, RNP(68kDa, A, C), Sm(B,B',D) SS-A/Ro(52kDa, 60kDa), SS-B/La, Scl-70, Centromere and Jo-1 in a single microwell.

General Description of the Device

The Varelisa ReCombi ANA Screen is an enzyme immunoassay for the qualitative determination of antinuclear antibodies in serum or plasma. Designed as a screen assay, it detects 8 antinuclear antibodies in a single microwell. The determination of antinuclear antibodies (ANA) is of central importance for the clinical diagnosis of rheumatic diseases. The presence of ANA suggests the possibility of rheumatic autoimmune diseases. These diseases include Systemic Lupus Erythematosus, Polymyositis/ Dermatomyositis, Scleroderma, Sjögren's Syndrome and Mixed Connective Tissue Diseases.

Varelisa® ReCombi ANA Screen, Test Principle

Varelisa ReCombi ANA Screen is an indirect noncompetitive enzyme immunoassay. The wells of a microplate are coated with human recombinant, native affinity purified nuclear antigens and dsDNA. Antibodies specific for the nuclear antigens present in a patient sample bind to these antigens.

In a second step the 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:

A correlation study was performed comparing the new device, Varelisa ReCombi ANA Screen Assay, to the predicate device, Varelisa ANA-8-Screen. 129 samples, including 10 ANA Human Reference Sera and 20 apparently healthy blood donors were assayed using both tests.

Seven monospecific sera, equivocal and positive for dsDNA-Ab in the Varelisa ReCombi ANA Screen were excluded from the evaluation of the agreement between the assays. It is an expected result that these 7 sera would test positive with the new device and negative with the predicate device because the new device, Varelisa ReCombi ANA Screen contains antigens for the detection of dsDNA, whereas the predicate device, Varelisa ANA-8-Screen, does not detect the presence of dsDNA antibodies. With the elimination of the 7 dsDNA positive sera, the agreement in this study was 97.5% (119 out of 122 (129-7) samples). Three discordant samples were borderline either to the upper or lower limit of the equivocal zone and differ with a maximum of 0.3 Ratio.

A linear regression analysis of these data gives the following equation:

$$y = 0.91x + 0.05 \quad R^2 = 0.93$$

		Varelisa ANA-8-Screen		
	n = 122	positive	equivocal	negative
VARELISA	positive	77	0	0
ReCombi	equivocal	1	4	2
ANA Screen	negative	0	0	38

7 dsDNA-Ab positive samples were excluded from the evaluation

The new device Varelisa® ReCombi ANA Screen shows an excellent correlation with the predicate device, Varelisa ANA-8-Screen, and adds the ability to detect antibodies against dsDNA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 1 2 1999

Ms. Karen E. Matis
Manager, Regulatory Affairs and
Quality Management
Diagnostics Division, US Operations
Pharmacia & Upjohn
7000 Portage Road
7425-248-01
Kalamazoo, Michigan 49001-0199

Re: K993108
Trade Name: Varelisa ReCombi ANA Screen EIA
Regulatory Class: II
Product Code: LJM
Dated: September 16, 1999
Received: September 17, 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 (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/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® ReCombi ANA Screen
510(k) Submission
Section 1. Indications For Use Statement

510(k) Number: K993108

Device Name: **Varelisa® ReCombi ANA Screen**

The Varelisa® ReCombi ANA Screen EIA kit is designed for the qualitative determination of eight antinuclear antibodies in human serum or plasma to aid in the diagnosis of systemic rheumatic diseases such as SLE (Systemic Lupus Erythematosus), Scleroderma (Progressive Systemic Sclerosis), MCTD (Mixed Connective Tissue Disease), SS (Sjögren's Syndrome) and Polymyositis/ Dermatomyositis. The Varelisa ReCombi ANA Screen detects antibodies against dsDNA, RNP(68kDa, A, C), Sm(B,B',D) SS-A/Ro(52kDa, 60kDa), SS-B/La, Scl-70, Centromere and Jo-1 in a single microwell.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993108