

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: K993109

Date of Summary Preparation: September 7, 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® ReCombi ANA Profile

Common Name: Antinuclear antibody immunological test

Classification:

<u>Product Name</u>	<u>Product Code</u>	<u>Class</u>	<u>CFR</u>
Varelisa® ReCombi ANA Profile	82LJM	II	866.5100

**Varelisa® ReCombi ANA Profile
510(k) Submission
Section 9. Summary of Safety and Effectiveness**

Substantial Equivalence to:

Varelisa® ANA Profile and Varelisa® dsDNA Antibodies Assays

Intended Use Statement:

The Varelisa ReCombi ANA Profile 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 Profile individually detects antibodies against dsDNA, RNP(68 kDa, A, C), Sm(B,B',D) SS-A/Ro(52 kDa, 60 kDa), SS-B/La, Scl-70, Centromere and Jo-1.

General Description of the Device

The Varelisa ReCombi ANA Profile is an enzyme immunoassay for the individual qualitative determination of 8 antinuclear antibodies in serum or plasma.

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.

Device Comparison:

A correlation study was performed comparing the new device, Varelisa ReCombi ANA Profile Assay, to the predicate devices, Varelisa ANA Profile and Varelisa dsDNA Antibodies Assay. 112 samples, including 20 apparently healthy blood donors were assayed using both tests.

A high degree of correlation is demonstrated in the correlation study. 107 out of 112 samples were found with the same result (96% agreement). Considering the individual parameters, 845 of 876 single determinations (96%) were in agreement between the new device and the predicate devices.

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In addition a total agreement is observed when comparing the results obtained for the ANA Reference Sera CDC-1 to CDC-10 from the Centers of Disease Control and Prevention. With both the new device and predicate devices, all 10 sera were found with the correct specificities.

These data clearly demonstrate that the new device, Varelisa® ReCombi ANA Profile is substantially equivalent to the predicate devices, Varelisa ANA Profile and Varelisa dsDNA Antibodies.

		Varelisa ANA Profile and Varelisa dsDNA Abs. Assay		
		n = 876 determinations	positive	equivocal
VARELISA ReCombi ANA Profile	positive	120	7	4
	equivocal	5	8	5
	negative	2	8	717

The new device Varelisa® ReCombi ANA Screen shows an excellent correlation with the predicate devices, Varelisa ANA Profile and Varelisa dsDNA Antibodies.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 12 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: K993109
Trade Name: Varelisa ReCombi ANA Profile
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.

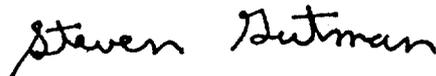
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style.

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

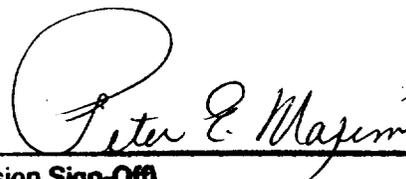
Enclosure

Varelisa® ReCombi ANA Profile
510(k) Submission
Section 1. Indications For Use Statement

510(k) Number: K993109

Device Name: **Varelisa ReCombi ANA Profile**

The Varelisa ReCombi ANA Profile 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 Profile individually detects antibodies against dsDNA, RNP(68 kDa, A, C), Sm(B,B',D) SS-A/Ro(52 kDa, 60 kDa), SS-B/La, Scl-70, Centromere and Jo-1.



(Division Sign-Off)
Division of Clinical Laboratory Devices K993109
510(k) Number K993109

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

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