9. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

MAY 1 4 2004

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: K040810

Date of Summary Preparation: March, 17 2004

Manufacturer:
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Device Name: Varelisa® Histone Antibodies

Common Name: Histone antinuclear autoantibody immunological test system

Classification

Product Name	Product Code	Class	CFR
Varelisa® Histone Antibodies	LJM	II	866.5100

Substantial Equivalence to

INOVA QUANTA Lite™ Histone

Intended Use Statement

The Varelisa Histone Antibodies EIA kit is designed for the semiquantitative and qualitative determination of IgG and IgM antibodies to histone in serum or plasma to aid in the diagnosis of systemic lupus erythematosus (SLE) or drug-induced lupus erythematosus (DIL).

General Description of the Device

Varelisa Histone Antibodies is an indirect noncompetitive enzyme immunoassay for the semiquantitative and qualitative determination of histone antibodies in human serum or plasma. Antibodies specific for histones present in the patient sample bind to the antigen.

The test kit contains microplate strips coated with purified human histone antigen, calibrators, positive and negative controls, enzyme-labeled conjugate, substrate and substrate stop solution, sample diluent and wash buffer.

Varelisa® Histone Antibodies Test Principle

Varelisa Histone Antibodies is an indirect noncompetitive enzyme immunoassay for the semiquantitative and qualitative determination of histone antibodies in human serum or plasma. The wells of a microtiterplate are coated with human histone antigen. Antibodies specific for histones present in the patient sample bind to the antigen.

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 conjugate-antibody-antigen 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

Both assays (the predicate and the new device) are indirect noncompetitive enzyme immunoassays for the semiquantitative determination of antibodies against Histone in serum. Both assays recommend the same sample dilutions and use comparable antigens and detection systems.

In accordance to the relevant scientific literature both assays state in the Intended Use, that the measuring of the antibodies against histone provides aid in the diagnosis of systemic lupus erythematosus (SLE) or drug-induced lupus erythematosus (DIL).

A difference between both assays is that the INOVA QUANTA Lite™ Histone IgG is only recommended for use in serum specimen while the PHARMACIA Varelisa Histone Antibodies is, besides a limitation given for the use of plasma preparations with heparin, intended for use with serum and plasma.

The Varelisa Histone Antibodies is directed against Anti-Histone IgG and IgM antibodies while the predicate device detects Anti-Histone IgG antibodies only.

The cut-off in the INOVA QUANTA Lite™ Histone IgG assay is evaluated by using a low and a high positive Standard and a grading of the results in negative, weak, moderate and strong positive. PHARMACIA Varelisa Histone Antibodies assay uses a set of six Calibrators and classifies the results as negative, equivocal and positive.

Laboratory equivalence

The comparability of INOVA QUANTA Lite™ Histone IgG and Varelisa Histone IgM/IgG Antibodies is supported by a data set including

- results obtained within a comparison study analyzing positive, equivocal and negative sera.
- results obtained for externally defined Calibrators.
- results obtained for samples from apparently healthy subjects (normal population).

The data show that the assay performs as expected from the medical literature.

In summary, all available data support that the new device, PHARMACIA Varelisa Histone IgM/IgG Antibodies Assay is substantially equivalent to the predicate device, INOVA QUANTA Lite™ Histone IgG Assay, and that the new device performs according to state-of-the-art expectations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 4 2004

Michael Linss, Ph.D.
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Freiburg,
Germany D 79111

Re: k040810
Trade/Device Name: Varelisa® Histone Antibodies
Regulation Number: 21 CFR 866.5100
Regulation Name: Antinuclear antibody immunological test system
Regulatory Class: Class II
Product Code: LJM
Dated: March 19, 2004
Received: March 29, 2004

Dear Dr. Linss:

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).

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

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

Enclosure

Varelisa® Histone Antibodies – New Device
510(k) Submission
Section 1. Indications for Use Statement

510(k) Number: K040810

Device Name: **Varelisa® Histone Antibodies**

Intended Use Statement

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(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) Maria Chan

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K040810