MAY 11 2004

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: K040452

Date of Summary Preparation: February 12, 2004

Manufacturer: Pharmacia Deutschland GmbH,
Diagnostics Division
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Device Name: Varelisa® ß2-Glycoprotein I Antibodies Screen

Common Name: ß2-Glycoprotein I autoantibody immunological test system

Classification

Product Name	Product Code	Class	CFR
Varelisa® ß2-Glycoprotein I Antibodies Screen	MSV	II	866.5660

Substantial Equivalence to

INOVA QUANTA Lite™ β2 GPI Screen

Intended Use Statement

The Varelisa β_2-Glycoprotein I Antibodies Screen EIA kit is designed for the qualitative determination of β_2-Glycoprotein I antibodies in human serum or plasma.

The presence of β_2-glycoprotein I antibodies can be used in conjunction with clinical findings and other laboratory tests to aid in the diagnosis of thrombotic disorders related to the primary Antiphospholipid Syndrome or occurring secondary to systemic lupus erythematosus (SLE) or other autoimmune diseases.

General Description of the Device

The Varelisa β_2-Glycoprotein I Antibodies Screen is an indirect noncompetitive enzyme immunoassay for the qualitative determination of antibodies against β_2-glycoprotein I in serum or plasma.

The test kit contains microplate strips coated with human purified ß2-glycoprotein I, calibrator, negative control, enzyme-labeled conjugate, substrate and substrate stop solution, buffered diluent and wash buffer.

Varelisa® ß2-Glycoprotein I Antibodies Screen Test Principle

Varelisa ß2-Glycoprotein I Antibodies Screen is an indirect noncompetitive enzyme immunoassay for the qualitative determination of ß2-glycoprotein I (IgG/IgM/IgA) antibodies in human serum or plasma. The wells of a microplate are coated with ß2-glycoprotein I. Antibodies specific for ß2-glycoprotein I 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

INOVA QUANTA Lite™ β2 GPI Screen (the predicate device) and PHARMACIA Varelisa β2-glycoprotein I Antibodies Screen (the new device) both are indirect noncompetitive enzyme immunoassays for qualitative detection of IgM, IgG and IgA antibodies against β2-glycoprotein I in serum. Both assays recommend the same sample dilutions and use comparable enzyme-linked conjugates and antigens.

Based on currently available data from the literature the measuring of the antibodies against β2-glycoprotein I not only provides aid in the diagnosis of thrombotic disorders secondary to systemic lupus erythematosus or other autoimmune diseases, but also aids in the diagnosis of the primary

antiphospholipid syndrome. Thus the intended use of Varelisa β2-glycoprotein I Antibodies Screen was adapted to the current state of scientific knowledge. The corresponding literature is cited in the directions for use.

A difference between both assays is that the INOVA QUANTA Lite™ β2 GPI Screen is only recommended for use in serum specimen while the PHARMACIA Varelisa β2-glycoprotein I Antibodies Screen is outlined for use with serum and plasma. Corresponding performance data underline the effectiveness of the assay with plasma as sample. Minor differences between both assays are restricted to contents of buffers and stop solution. The INOVA QUANTA Lite™ β2 GPI Screen contains an additional assay control and the assay is evaluated by using the decision point method. PHARMACIA Varelisa β2-glycoprotein I Antibodies Screen assay uses an ODcut-off. Corresponding performance data show the comparability of the results.

Laboratory equivalence

The comparability of INOVA QUANTA Lite™ β2 GPI Screen and PHARMACIA Varelisa β2-glycoprotein I Antibodies Screen 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. Furthermore the performance data show that the device is suitable for serum and plasma samples.

In summary, all available data support that the new device, PHARMACIA Varelisa β2-glycoprotein I Antibodies Screen Assay is substantially equivalent to the predicate device, INOVA QUANTA Lite™ β2 GPI Screen 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 11 2004

Michael Linss, Ph.D.
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Diagnostics Division
Munzinger Strasse 7
Freiburg,
Germany D-79111

Re: k040452
Trade/Device Name: Varelisa® ß2 Glycoprotein I Antibodies Screen
Regulation Number: 21 CFR 866.5660
Regulation Name: Multiple autoantibodies immunological test system
Regulatory Class: Class II
Product Code: MSV
Dated: April 27, 2004
Received: April 30, 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).

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 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
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Varelisa® ß2-Glycoprotein I Antibodies Screen – New Device
510(k) Submission
Section 1. Indications for Use Statement

510(k) Number: K040452

Device Name: **Varelisa® ß2-Glycoprotein I Antibodies Screen**

Intended Use Statement

The Varelisa β2-Glycoprotein I Antibodies Screen EIA kit is designed for the qualitative determination of β2-Glycoprotein I antibodies in human serum or plasma. The presence of β_2-glycoprotein I antibodies can be used in conjunction with clinical findings and other laboratory tests to aid in the diagnosis of thrombotic disorders related to the primary Antiphospholipid Syndrome or occurring secondary to systemic lupus erythematosus (SLE) or other autoimmune diseases.

Maria Chan
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K040452

(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)