9. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

MAR 13 2009

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: K083188

Date of Summary Preparation:

Manufacturer:
Phadia GmbH
Munzinger Strasse 7
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Company Contact Person:
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Device Name: Varelisa ReCombi ANA Screen

Common Name: Antinuclear antibody immunological test system

Classification

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

Substantial Equivalence to

Varelisa® ReCombi ANA Screen: 510(k) number: K993108

Intended Use Statement of the New Device

Intended use/Indication for use

The Varelisa ReCombi ANA Screen EIA kit is designed for the qualitative determination of eight antinuclear antibodies in human serum or plasma (citrate/EDTA) 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, U1RNP (RNP70, A, C), Sm, SS-A/Ro (52 kDa,60 kDa), SS-B/La, Scl-70, CENP-B and Jo-1 in a single microwell.

Special condition for use statement

The device is for prescription use only.

Special instrument requirements

A microplate reader capable of measuring OD at 450 nm and 620 nm is required.

General Description of the New Device

The Varelisa ReCombi ANA Screen is an enzyme-linked immunosorbent assay (ELISA) for the qualitative determination of antinuclear antibodies in serum and plasma (citrate/EDTA). Designed as a screening assay, it detects eight 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 Erythemtosus (SLE), Polymyositis/ Dermatomyositis, Scleroderma, Sjögren's Syndrome and Mixed Conective Tissue Diseases.

Test Principle of the New Device

Varelisa ReCombi ANA Screen is an indirect noncompetitive enzyme immunoassay for the qualitative determination of 8 antinuclear antibodies in serum or plasma (citrate/EDTA). The wells of a microplate are coated with human recombinant nuclear antigens, synthetic peptides and dsDNA. Antibodies specific for the nuclear antigens present in a patient sample bind to these nuclear 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 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

The new device is developed as successor of the predicate device. Both assays share the same assay principle and indications for use. They are indirect

noncompetitive enzyme immunoassays for qualitative determination of IgG antibodies against antinuclear antigens in serum and plasma. Both assays recommend the same sample dilutions and use identical reagents (including the conjugate). In accordance to the relevant scientific literature both assays state in the Intended Use, that the measuring of antinuclear antibodies aids in the diagnosis of Connective Tissue Diseases such as SLE (systemic lupus erythematosus), scleroderma (progressive systemic sclerosis), MCTD (mixed connective tissue disease), SS (Sjögren's syndrome) and PM/DM (polymyositis/ dermatomyositis).

Differences do exist but do not affect the tenor of the "Intended Use" and do not raise new types of "Safety and Effectiveness" questions. The new device uses a synthetic peptide derived from the human SmD protein instead of Sm antigen purified from calf thymus. Minor differences pertain to increased volumina of the reagents and leaving out the prewashing step of the antigen strips. The Wash buffer no longer contains NaN_3 and the substrate TMB is of lower concentration because the substrate incubation step has been increased to 30 min.

Laboratory equivalence

The comparability of predicate device and new device is supported by a data set including

- results obtained for clinically defined sera and for international reference sera.
- results obtained for samples from apparently healthy subjects (normal population).
- Results obtained within a comparison study analyzing 150 disease controls and 103 CTD samples.

In summary, all available data support that the new device is substantially equivalent to the predicate device and that the new device performs according to state-of-the-art expectations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Phadia US Inc
c/o Mr. Martin R. Mann
Regulatory Affairs Manager
4169 Commercial Ave
Portage, Michigan 49002

MAR 13 2009

Re: k083188
Trade/Device Name: Varelisa ® ReCombi ANA Screen
Regulation Number: 21 CFR 866.5100
Regulation Name: Antinuclear antibody immunological test system
Regulatory Class: II
Product Code: LJM
Dated: October 24, 2008
Received: October 29, 2008

Dear Mr. Mann:

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 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. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 advice for your device on the labeling regulation, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240- 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For question regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR), please contact the Division of Surveillance Systems at 240-276-3464. You many obtain other general information on your responsibilities under the Act from the Division of Small Manufactuers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k083188

Device Name: Varelisa ReCombi ANA Screen

Indication For Use:

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Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Maria M Chan

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 083188