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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: K041357

Date of Summary Preparation: May 12, 2004

Manufacturer:
Sweden Diagnostics (Germany) GmbH
Munzinger Strasse 7
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Company Contact Person:
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Device Name: Varelisa® Gliadin IgG Antibodies

Common Name: Gliadin antibodies radioallergosorbent (RAST) immunological test system

Classification

Product Name	Product Code	Class	CFR
Varelisa® Gliadin IgG Antibodies	MST	II	866.5750

Substantial Equivalence to

INOVA QUANTA Lite™ Gliadin IgG

Intended Use Statement of the New Device

The Varelisa Gliadin IgG Antibodies EIA kit is designed for the semiquantitative and qualitative determination of gliadin (IgG) antibodies in serum or plasma to aid in the diagnosis of certain gluten sensitive enteropathies such as celiac disease and dermatitis herpetiformis.

General Description of the New Device

Varelisa Gliadin IgG Antibodies is an indirect noncompetitive enzyme immunoassay for the semiquantitative and qualitative determination of gliadin (IgG) antibodies in human serum or plasma. Antibodies specific for gliadin (IgG) present in the patient sample bind to the antigen.

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

Test Principle of the New Device

Varelisa Gliadin IgG Antibodies is an indirect noncompetitive enzyme immunoassay for the semiquantitative and qualitative determination of gliadin (IgG) antibodies in human serum or plasma. The wells of a microplate are coated with gliadin antigen. Antibodies specific for gliadin (IgG) 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 IgG antibodies against Gliadin 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 IgG antibodies against gliadin provides aid in the diagnosis of celiac disease and dermatitis herpetiformis.

A difference between both assays is that the predicate device is only recommended for use in serum specimen while the new device is intended for use with serum and plasma.

The cut-off in the predicate device 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. The new device assay uses a set of six Calibrators and classifies the results as negative, equivocal and positive.

Laboratory equivalence

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

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

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

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Michael Linss, Ph.D
Manager, Compliance and Quality
Sweden Diagnostics (Germany) GmbH
Munzinger Strasse 7
D-79111 Freiburg, GERMANY

Re: k041357
Trade/Device Name: Varelisa® Gliadin IgG Antibodies
Regulation Number: 21 CFR 866.5750
Regulation Name: Radioallergosorbent (RAST) Immunological test system
Regulatory Class: Class II
Product Code: MST
Dated: July 21, 2004
Received: July 23, 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,

Robert L. Becker, Jr., M.D., 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

Indications for Use

510(k) Number: **K041357**

Device Name: **Varelisa® Gliadin IgG Antibodies**

Indications For Use:

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Prescription Use __√__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041357