K053383

MAR 2 9 2006

Premarket Notification 510(k) Summary

1. Submitted by :

Name:	Biomedical Diagnostics S.A (bmd)
Contact Person:	Christelle COURIVAUD Regulatory Affairs Manager
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Establishment Registration Number:	3003935253

US Agent correspondent:

Hoppe Regulatory Consultants
Ms P. Ann HOPPE
2335 Massey Lane
Decatur GA 30033 USA
Phone: 404 248 0002
E-mail: Hoppe Regulatory@cs.com

2. Device Name

Trade/Proprietary Name : **FIDIS™ CELIAC**

Common/Usual Name :

MX004 - FIDIS™ CELIAC IgA and IgG: Detection test of IgA and/or IgG isotypes against gliadin and tTG (tissue Transglutaminase enzyme)

MX009 - FIDIS™ CELIAC IgG: Detection test of IgG isotype against gliadin and tTG (tissue transglutaminase enzyme)

MX010 - FIDIS™ CELIAC IgA: Detection test of IgA isotype against gliadin and tTG (tissue transglutaminase enzyme)

Classification Name: Immunology and Microbiology Devices

S.A au Capital de 2 755.46 Euros
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Siret: 339 685 612 00048-APE: 514N
N° TVA Intracommunautaire: FR 68 339 685 612

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3. Predicate Devices

510K Number	Device Classification Name	Manufacturer Name
K964986	QuantaLite™ IgA Gliadin	INOVA Diagnostics, INC
K982366	QuantaLite™ IgA TTG	INOVA Diagnostics, INC
K041357	Varelisa® IgG Gliadin	Sweden Diagnostics, GMBH
K041173	Celikey® IgG TTG	Sweden Diagnostics, GMBH

4. Intended use of the device

The **FIDIS™ CELIAC** kits are quantitative homogeneous fluorescent-based microparticles immunoassays using flow cytometry readings. They are designed for the simultaneous detection of human isotype IgA and/or IgG autoantibodies directed against Gliadin and tissue Transglutaminase Enzyme.
The presence of tissue Transglutaminase and Gliadin autoantibodies can be used to aid in the diagnosis of Celiac disease.

5. Description of the Device

The assay kits consist of:
- a mixture of color-coded microspheres respectively sensitized by Gliadin (Glia) or tissue transglutaminase (tTG),
- a ready to use phycoerythrin conjugated anti-human IgA or phycoerythrin conjugated anti-human IgG,
- a ready to use calibrator IgA or calibrator IgG,
- a positive control IgA or positive control IgG to be diluted,
- a negative control to be diluted,
- a 10X concentrated PBS-Tween.

Rk: Calibrators, positive and negative controls are diluted human sera.

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6. Summary of the technological characteristics of the device compared to the predicate device

The **FIDIS™ System** is a fully integrated and automated system for immunodiagnostic testing.
FIDIS™ System comprised of FIDIS flow cytometer, XYP platform for automatic sampling into the analyser, the analyzer itself, a SD pump, some assay products and a software **MLX-BOOSTER**.

The **FIDIS™ CELIAC** kits resemble traditional EIA, but allow simultaneous detection and identification of several antibodies in a single well.
The serum sample is combined with a mix of microspheres individually coated with gliadin or tTG and form an antigen / antibody complex.
After washing, this complex is incubated with phycoerythrin labeled anti-human IgG or IgA. If autoantibodies are present in the sample, the final sandwich complex antigen / human antibody / anti-human antibody will form.
Reactions are directly analysed by the cytometer and calculated in biological units using specific data software (**MLX-BOOSTER**).

The **FIDIS™ Instrument** is able to distinct the specific color-coded of each microsphere types and it could associated the microsphere type with the individual tested antigen.
The **FIDIS™ Instrument** could quantify the fluorescence of the antibody captured by each microsphere. Measurement of the fluorescent signal from the final reaction complex allows the quantification of the presence or absence of autoantibodies.

It's a simple (just two steps), quick (2 x 30 minutes for the two incubations) and multiple parameter test.

7. Testing

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

- results obtained within a comparison study analysing positive, equivocal and negative sera
- results obtained for samples from apparently healthy subject (normal population)
- results obtained for samples from samples with potential biological cross reactivity

8. Conclusions

In conclusion, all available data support that the new devices, **FIDIS™ CELIAC** kits are substantially equivalent to the predicate devices.

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510(k) Number (if Known): k053383

Device Name: **FIDIS™ CELIAC**

Indications For Use:

The **FIDIS™ CELIAC** kit is a **semi-quantitative** homogeneous fluorescent-based microparticles immunoassay using flow cytometry readings. It is designed for the simultaneous detection of human isotype **IgA or** IgG **antibodies** directed against Gliadin and tissue Transglutaminase Enzyme.

Clinical utility:

The presence of these antibodies can be used in conjunction with clinical findings to aid in diagnosis of Celiac disease.
The FIDIS™ CELIAC kit is to be used in serum only

The FIDIS™ CELIAC Kits are to be used on FIDIS™ Analyzer, software and washer.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Professional Use _____

Prescription Use ____X__ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 9 2006

Biomedical Diagnostics (BMD) SA
c/o Ms. Christelle Courivaud
Regulatory Manager
Actipole 25
4-6 bd de Beaubourg
77435 Marne La Vallée cedex 2
France

Re: k053383
Trade/Device Name: FIDIS™ Celiac
Regulation Number: 21 CFR 866.5660
Regulation Name: Multiple autoantibodies, immunological test system
Regulatory Class: Class II
Product Code: MST, MVM
Dated: November 28, 2005
Received: December 5, 2005

Dear Ms. Christelle:

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.

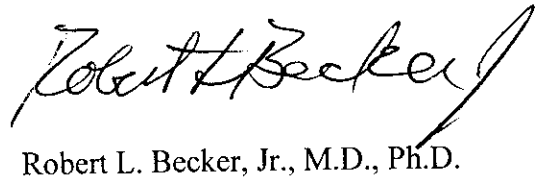
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0484. 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/industry/support/index.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

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Maria Chan
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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