

MAY 2 2006



**Premarket Notification 510(k) Summary**

**Assigned 510(k) Number: k060380**

**1. Submitted by :**

Name Biomedical Diagnostics S A (bmd)  
Contact Person Christelle COURIVAUD  
Regulatory Affairs Manager  
Address Actipole 25, 4-6 Bld de Beaubourg  
77435 Marne-La-Vallée Cedex 2  
FRANCE  
Telephone 33 (0)1 64 62 10 12  
Fax: 33 (0)1 64 62 09 66  
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™ dsDNA**  
*Common Usual Name :* **MX005 - FIDIS™ dsDNA: Detection test of autoantibodies directed against double stranded DNA (dsDNA)**  
*Classification Name:* Immunology and Microbiology Devices

**3. Predicate Devices**

510K Number	Device Classification Name	Manufacturer Name
K950031	Varelixo dsDNA antibodies	Sweden Diagnostics, GHMH

S.A au Capital de 2 755 46 Euros  
RCS Meaux: J1339 685 612  
Siret: 339 685 612 00048-APE 514N  
N° TVA Intracommunautaire: FR 68 339 685 612

*Registered Office*  
Actipole 25  
4-6 Bld de Beaubourg  
77435 Marne La Vallée cedex 2

**Page 1 of 3**  
Tel: 33 (0)1 64 62 10 12  
Fax : 33 (0)1 64 62 09 66  
Email: [husd@bmd-net.com](mailto:husd@bmd-net.com)  
Internet: [www.bmd-net.com](http://www.bmd-net.com)



#### 4. Intended use of the device

The FIDIS™ dsDNA kit is a semi-quantitative homogeneous fluorescent-based microparticles immunoassays using flow cytometry readings. It is designed for the detection of antibodies directed against double stranded DNA (dsDNA).

The presence of these antibodies can be used to aid in the diagnosis of SLE.

#### 5. Description of the Device

The assay kits consist of:

- a vial of color-coded microspheres coupled with dsDNA
- a ready to use anti-human IgG coupled to phycoerythrin,
- a ready to use calibrator titrated for the specificity,
- a 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

#### 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™ dsDNA kit resembles traditional EIA and allows the detection and identification of antibodies against dsDNA

1. Diluted patient sera and microsphere suspension are thoroughly mixed in the 96 well microtiter plate. dsDNA specific antibodies in the patient sera, if present, bind to the immobilised antigen on the beads. Any unbound material is removed by performing a wash step.
2. Phycoerythrin-conjugated goat anti-human IgG is added to the plate and a further incubation performed. The conjugated anti-human IgG binds to the dsDNA specific antibodies immobilised on the microsphere surface to form an antigen/antibody complex

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Registered Office  
Actipole 25  
4-6 bd de Beaubourg  
77435 Merse La Vallée cedex 2

Tel: 33 (0)1 64 62 10 12  
Fax: 33 (0)1 64 62 09 66  
Email: [bmd@bmd-net.com](mailto:bmd@bmd-net.com)  
Internet: [www.bmd-net.com](http://www.bmd-net.com)



3. The bead suspension is then analysed by the FIDIS™ Instrument and reactions are directly calculated in biological units using specific data software (**MLX-BOOSTER**).

The **FIDIS™ Instrument** is able to distinct the specific code-colored of the microsphere 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) and quick (2 x 30 minutes for the two incubations).

#### 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™ dsDNA** kit is substantially equivalent to the predicate devices.

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RCS Meuse. N 339 685 612  
Siret: 339 685 612 00048-APE: 514N  
N° TVA Intracommunautaire: FR 68 339 685 612

Registered Office  
Autopole 25  
4-6 bd de Strasbourg  
77415 Marne La Vallée cedex 2

Tel : +33 (0) 64 62 10 12  
Fax : +33 (0) 64 62 09 66  
Email: [bmd@bmd-net.com](mailto:bmd@bmd-net.com)  
Internet: [www.bmd-net.com](http://www.bmd-net.com)



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Biomedical Diagnostics (BMD) SA  
c/o Ms. Christelle Courivaud  
Regulatory Manager  
Actipole 25  
4-6 Bld de Beaubourg  
77435 Marne La Vallée cedex2  
France

MAY 2 2006

Re: k060380

Trade/Device Name: FIDIS™ dsDNA  
Regulation Number: 21 CFR 866.5100  
Regulation Name: Antinuclear antibody immunological test system  
Regulatory Class: Class II  
Product Code: LSW  
Dated: January 30, 2006  
Received: February 22, 2006

Dear Ms. Courivaud:

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.

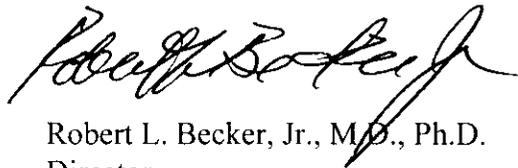
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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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



510(k) Number (if Known): k060380

Device Name: FIDIS™ dsDNA

Indications For Use:

The **FIDIS™ dsDNA** kit is a semi-quantitative homogeneous fluorescent-based microparticles immunoassay using flow cytometry readings. It is designed for the detection of antibodies directed against double stranded DNA (dsDNA)

Clinical utility:

The test system is used on serum samples as an aid in the diagnostic of systemic lupus erythematosus (SLE), in conjunction with clinical findings and other laboratory tests.

The **FIDIS™ dsDNA** kit is to be used on FIDIS™ Analyser, 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   
(Per 21 CFR 801.109)

OR Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

Mano Char  
Division Sign-Off

Office of In Vitro Diagnostic  
Device Evaluation and Safety

510(k) k060380