biomedical diagnostics

MAR 1 3 2006

Premarket Notification 510(k) Summary

Assigned 510(k) Number: K053653

1. Submitted by :

Name:	Biomedical Diagnostics S.A (bmd)
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Establishment Registration Number:	3003935253

US Agent correspondent:

Hoppe Regulatory Consultants
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2. Device Name

Trade/Proprietary Name : **FIDIS™ CONNECTIVE 10**

Common/Usual Name : **MX006 - FIDIS™ CONNECTIVE 10**: Detection test of 10 autoantibody specificities: double stranded DNA (dsDNA), SSA 60kDa, SSA 52kDa, SSB, Sm, Sm/RNP, Scl70, Jo-1, Ribosomes and Centromeres.

Classification Name: Immunology and Microbiology Devices

3. Predicate Devices

510K Number	Device Classification Name	Manufacturer Name
K950031	Varelisa dsDNA antibodies	Sweden Diagnostics, GBMH
K944169	Varelisa RO (SS-A) antibodies	Sweden Diagnostics, GBMH
K944168	Varelisa LA (SS-B) antibodies	Sweden Diagnostics, GBMH
K042629	Varelisa SM antibodies	Sweden Diagnostics, GBMH
K993589	Varelisa RNP antibodies	Sweden Diagnostics, GBMH
K944173	Varelisa JO1 antibodies	Sweden Diagnostics, GBMH
K944172	Varelisa SCL-70 antibodies	Sweden Diagnostics, GBMH
K944171	Varelisa CENTROMERE antibodies	Sweden Diagnostics, GBMH
K981237	QuantaLite RIBOSOME P ELISA	INOVA Diagnostics, Inc

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

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

4. Intended use of the device

The **FIDIS™ CONNECTIVE 10*** kit is a semi-quantitative homogeneous fluorescent-based microparticles immunoassays using flow cytometry readings. It is designed for the simultaneous detection of 10 autoantibody specificities: double stranded DNA (dsDNA), SSA 60kDa, SSA 52kDa, SSB, Sm, Sm/RNP, Scl70, Jo-1, Ribosomes and Centromeres.

(* antibodies to dsDNA, Sm, Sm/RNP, SS-A, SS-B, Scl70, Jo1, Ribosomes and Centromeres can be reported using this assay).

The test system is used to screen serum samples and detect the presence of anti-nuclear antibodies associated with connective diseases (systemic lupus erythematosus (SLE), Sjogren's syndrome, mixed connective tissues disease (MCTD) scleroderma, dermatomyositis, polymyositis and CREST syndrome).

5. Description of the Device

The assay kits consist of:
- a mixture of color-coded microspheres sensitized respectively by dsDNA, SSA 60kDa, SSA 52kDa, SSB, Sm, Sm/RNP, Scl70, Jo-1, Ribosomes and Centromeres.
- a ready to use anti-human IgG coupled to phycoerythrin,
- a ready to use calibrator titered for each 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 **MLX-BOOSTER** software.

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The **FIDIS™ CONNECTIVE 10** kit resembles traditional EIA, but allows simultaneous detection and identification of several antibodies in a single well.

1. Diluted patient sera and multiplexed bead suspension are thoroughly mixed in the 96 well microtiter plate. Antigen specific antibodies in the patient sera, if present, bind to the immobilised antigen on one or more of the bead sets. 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 antigen specific antibodies immobilised on the microsphere surface to form an antigen/antibody complex.
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 distinguish the specific color-code of each microsphere types and it could associate the microsphere type with the individual tested antigen.
The **FIDIS™ Instrument** can 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 (10 specific antibodies per patient sample).

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™ CONNECTIVE 10** kit is substantially equivalent to the predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Christelle Courivaud
Regulatory Manager
Biomedical Diagnostics
Actipole 25
4-6 BLD De Beaubourg
Marne La Vallee Cedex 2
France 77435

MAR 13 2006

Re: k053653
Trade/Device Name: FIDIS™ Connective 10
Regulation Number: 21 CFR § 866.5100
Regulation Name: Antinuclear antibody immunological test system
Regulatory Class: II
Product Code: LLL, LKJ, LKO, LKP, LSW, LJM, MQA
Dated: February 17, 2006
Received: February 28, 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 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 (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., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

bmd
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510(k) Number: K053653

Device Name: **FIDIS™ CONNECTIVE 10**

Indications For Use:

The **FIDIS™ CONNECTIVE 10*** kit is a semi-quantitative homogeneous fluorescent based microparticles immunoassay using flow cytometry readings. It is designed for the simultaneous detection of autoantibody specificities: double stranded DNA (dsDNA), SSA (60 kDA and 52 kDA), SSB, Sm, Sm/RNP, Scl-70, Jo-1 ribosome and centromere in human serum. (*Antibodies to dsDNA, SSA, SSB, Sm, Sm/RNP, Scl-70, Jo-1, ribosome and centromere can be reported using this assay).

Clinical utility:

The test system is used to screen serum samples and detect the presence of antinuclear antibodies associated with connective diseases systemic lupus erythematosus (SLE), Sjögren's syndrome, mixed connective tissue disease (MCTD), scleroderma, dermatomyositis, and CREST syndrome, in conjunction with clinical findings and other laboratory tests.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

LPReeves for M. Chan
Division Sign-Off

Office of In Vitro Diagnostic Dev
Evaluation and Safety

510(k) K053653

Professional Use _____

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

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