DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 2006

Biomedical Diagnostics (BMD) SA
c/o Mrs. Christelle Courivaud
Regulatory Manager
Actipole 25, 4 Bld de Beaubourg
77435 Marne La Vallée Cedex 2
France

Re: k053012
Trade/Device Name: FIDIS™ VASCULIS*
Regulation Number: 21 CFR 866.5660
Regulation Name: Multiple autoantibodies, immunological test system
Regulatory Class: Class II
Product Code: MOB, MVJ
Dated: October 21, 2005
Received: October 26, 2005

Dear Mrs. 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.

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

bmd
biomedical diagnostics

510(k) Number (if Known): K053012

Device Name: **FIDIS™ VASCULITIS***

Indications For Use:

The **FIDIS™ VASCULITIS*** kit is a semi-quantitative homogeneous fluorescent-based microparticles immunoassay using flow cytometry readings. The test system is used to detect in patient serum samples the presence of anti-neutrophil cytoplasm antibodies (ANCA) directed against Myeloperoxidase (*MPO*) and Serine Proteinase 3 (*PR3*) ; and anti-glomerular basement membrane (GBM) antibodies.

The results of the **FIDIS™ VASCULITIS* test** are to be used in conjunction with the clinical findings and the other laboratory tests to aid in the diagnosis of various primary systemic small vessel vasculitis.

Clinical utility:

The presence of anti-MPO and anti-PR3 antibodies associated primary systemic small vessel vasculitis: Wegener's granulomatosis, Churg Strauss syndromes, microscopic periarteritis and idiopatic crescentic glomerulonephritis; and the presence of anti-GBM antibodies is associated with Goodpasture's syndrome.

FIDIS™ VASCULITIS* kit is used on the FIDIS Analyser, MLX-BOOSTER Software and Washer.

FIDIS™ VASCULITIS* kit could be used with **CARIS™ system** (diluting and dispensing device).

This test is for in vitro diagnostic use.

* Detection of the serologic markers for primary systemic small vessel vasculitis (ANCA) and for Goodpasture syndrome (GBM)

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

Concurrence of CDRH, Office of Device Evaluation (ODE) Maria M Chan

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K053012

Professional Use _____

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

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

Adresse Postale:
Actipole 25
4 bd de Beaubourg
77435 Marne La Vallée cedex 2

Tél: 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