DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Biomedical Diagnostics (BMD) SA
c/o Ms Christelle Courivaud
Assurance Quality/Regulatory Affairs Manager
Actipole 25 - 4 Bld de Beaubourg
77435 Marne-La-Vallée cedex 2
France

OCT 3 - 2005

Re: k050286
Trade/Device Name: FIDIS™ Connective 8*
Regulation Number: 21 CFR 866.5100
Regulation Name: Antinuclear antibody, antigen and control
Regulatory Class: Class II
Product Code: LLL, LKJ, LKO, LKP, LSW
Dated: February 4, 2005
Received: February 7, 2005

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.

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 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

510(k) Number (if Known): K050286

Device Name: **FIDIS™ CONNECTIVE 8**

Indications For Use:

The **FIDIS™ CONNECTIVE 8*** kit is a semi-quantitative homogeneous fluorescent-based microparticles immunoassay using flow cytometery readings. It is designed for the simultaneous detection of 8 autoantibody specificities: double stranded DNA (dsDNA), SSA 60 kDa, SSA 52 kDa, SSB, Sm, Sm/RNP, Scl70 and Jo-1 (*antibodies to dsDNA, Sm, Sm/RNP, SS-A, SS-B, Scl-70 and Jo-1 can be reported using this assay).

Clinical utility:

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 tissue disease (MCTD), scleroderma, dermatomyositis, polymyositis 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)

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: brad@brad-net.com
Internet : www.brad-net.com

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K050286