DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Eileen McCafferty
Regulatory Affairs Manager
Axis-Shield Diagnostics
Lune Place
The Technology Park
Dundee DD2 1XA
SCOTLAND

JUN 19 2003

Re: k031177
Trade/Device Name: Diastat™ Anti-BETA 2 GLYCOPROTEIN 1 IgM
(Diastat™ Anti-b2 GP1 IgM)
Regulation Number: 21 CFR § 866.5660
Regulation Name: Multiple Autoantibodies Immunological Test System
Regulatory Class: II
Product Code: MSV
Dated: April 10, 2002
Received: April 29, 2002

Dear Ms. McCafferty:

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

+ **INDICATIONS FOR USE**

510(k) number if known.....K031177

Device Name... Diastat™ Anti-BETA 2 GLYCOPROTEIN 1 IgM
(Diastat ™ Anti- b2 GPI IgM)

Indications for Use The Diastat ™Anti Beta 2 GLYCOPROTEIN I IgM test is a semi-quantitative/qualitative enzyme-linked immunosorbent Assay (ELISA) for the detection the IgM class of autoantibodies to b2 GP1 in human serum, or sodium citrate, EDTA(K2), and lithium heparin anti-coagulated plasma.

It is intended to aid in the assessment of thrombotic risk in patients with autoimmune disease associated with thrombotic disorders such as those with Primary Anti Phospholipid Syndrome (PAPS) or secondary to Systemic Lupus Erythematosus and is not definitive in isolation. Autoantibody levels represent one parameter in a multicriterion diagnostic process.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

Prescription Use..✓..... 510(k) K031177 OR Over - the - Counter Use.....
Per 21 CFR 801. 109