DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 6 2002

Ms. Eileen McCafferty
Regulatory Affairs Manager
Axis-Shield Diagnostics Limited
Luna Place
The Technology Park
Dundee DD2 1XA
Scotland

Re: k020156
Trade/Device Name: Axis-Shield DIASTAT™ Total Anti-Cardiolipin
Regulation Number: 21 CFR § 866.5660
Regulation Name: Multiple Autoantibodies Immunological Test System
Regulatory Class: II
Product Code: MID
Dated: January 15, 2002
Received: January 17, 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 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

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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 Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

MAR 6 2002

510(k) number if known...K020156

Device Name... Axis-Shield Total anti-Cardiolipin Elisa

Indications for Use The test is for the semi-quantitative combined detection of IgG, IgM and IgA autoantibodies specific for the Phospholipid Cardiolipin in huma serum or plasma (EDTA, citrate, heparin)

The kit is intended to assess total anti-Cardiolipin autoantibody levels in patients where this information is useful in diagnosis, particularly as an aid in the assessment of thrombotic risk in patients with systemic lupus erythematosus or other lupus - like disorders.

Total anti-Cardiolipin levels represent one parameter in a multi–criterion diagnostic process.

Sonsan S. Altaie

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K020156

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use..... ✓ ..... OR Over - the - Counter Use.....
Per 21 CFR 801. 109