DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 13 2004

Ms. Eileen McCafferty
Regulatory Affairs Manager
Axis-Shield Diagnostics Ltd.
The Technology Park
Dundee
DD2 1XA
SCOTLAND, UK

Re: K020348

Trade/Device Name:	Abbott AxSYM® anti-Thyroid peroxidase (anti-TPO) Microparticle Enzyme Immunoassay (MEIA)
Regulation Number:	21 C.F.R. 866.5870
Regulation Name:	Thyroid antibody immunological test system
Product Codes:	JZO, JIT, JJX
Dated:	January 31, 2002
Received:	February 4, 2002

Dear Ms. McCafferty:

This letter corrects our substantially equivalent letter of May 2, 2002, regarding omission of the product codes for both the AxSYM Calibrator (JIT) and Controls (JJX).

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 (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 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 continue 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 and additionally Part 809.10) for *in vitro* diagnostic devices, please contact the Office of Compliance at (301) 594-3084 x177. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman, M.D.

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

Enclosures

INDICATIONS FOR USE

510(k) number if known.....K020348

Device Name... ...Abbott AxSYM® anti-Thyroid-peroxidase (anti-TPO) Microparticle Enzyme Immunoassay (MEIA)

Indications for Use The test is for the quantitative measurement of the IgG class of auto-antibodies to anti-Thyroid-peroxidase (anti-TPO) in human serum or plasma (EDTA or heparin) to aid in the diagnosis of thyroid disease.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chadha Menon

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020348

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

Optional format 1 - 2 - 96