510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following summary of safety and effectiveness provides details to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

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Contact Person: Susan Leonard

Email address: susan_leonard@uk.axis-shield.com

Date Prepared: July 7th, 2004

Device Name

Proprietary Name: Abbott AxSYM® Testosterone Microparticle Enzyme Immunoassay (MEIA) test

Common name: Microparticle Enzyme Immunoassay (MEIA) for the determination of Testosterone.

Classification name: Testosterone test system

Predicate Device

Substantial equivalence to the Roche Elecsys® Testosterone assay (K964889) is claimed.

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Device Description
Competition format.
Microparticle Enzyme Immunoassay (MEIA) for use on Abbott AxSYM® system.

Assay procedure:

- Incubate the sample with the antibody-coated microparticles.
- Add testosterone alkaline phosphatase conjugate and incubate.
- Transfer to matrix cell.
- Wash to remove unbound substances.
- Add substrate.
- Measure fluorescent product.

Intended Use

A Microparticle Enzyme Immunoassay (MEIA) for the quantitative determination of testosterone in human serum and plasma on the AxSYM System.

Comparison to Predicate Device

The AxSYM®Testosterone immunoassay is substantially equivalent to the Roche Elecsys® Testosterone assay cleared under K964889. Both products are intended for use in the quantitative determination of testosterone.

The following information is presented in the Premarket Notification [510(k)] for AxSYM® Testosterone to support a substantially equivalent determination.

Similarities:

- Intended use
- Operating principles (competitive assay format using antigen-antibody interactions)
- Sample type (serum and plasma)
- Quantitative assay
- For use on automated instruments

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Comparison to Predicate Device (continued)

Differences:

Parameter	Submission Device AxSYM® Testosterone	Predicate Device Elecsys® Testosterone
Technology Format	Microparticle Enzyme Immunoassay (MEIA).	Electrochemiluminescence Immunoassay (ECLIA).
Capture Antibody	Anti-testosterone (mouse, monoclonal) antibody coated microparticles.	Biotinylated monoclonal anti-testosterone antibody (mouse). Becomes bound to streptavidin coated microparticles.
Competition Antigen	Testosterone:Alkaline Phosphatase conjugate.	Testosterone derivative labelled with a ruthenium complex.
Substrate	4-Methylumbelliferyl phosphate.	Not applicable.
Assay End-Point	Fluorescence	Electrochemiluminescence
Quantitation	Results are determined from a standard calibration curve (0, 0.2, 1.0, 2.5, 7.0, 15.0 ng/mL) generated and stored on the instrument.	Results are determined from a calibration curve generated on the instrument via a two-point calibration and a master curve provided via the reagent barcode.
Standardisation	Concentration is standardised gravimetrically and confirmed by GCMS (Gas Chromatography Mass Spectrometry).	The method has been standardised via ID-GCMS (Isotope Dilution Gas Chromatography Mass Spectrometry).
Reagent stability	Up to stated expiration date when stored at 2-8°C. 2 weeks on-board the AxSYM.	Up to stated expiration date when stored at 2-8°C. 4 weeks on-board the Elecsys 1010. 8 weeks on-board the E170/Elecsys 2010.

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Comparison to Predicate Device (continued)

Revised

Performance Characteristics:

Parameter	Submission Device AxSYM® Testosterone	Predicate Device Elecsys®Testosterone
Precision	Within-run CV of 3.9% to 8.3%. Total CV of ≤14% for samples with testosterone concentrations ≥0.85ng/ml and ≤10% for samples ≥2.10ng/ml.	Within-run CV of 0.9% to 4.6% Total CV of 1.6 to 7.4 % from 0.24 to 7.01 ng/mL.
Functional Sensitivity	≤0.2ng/ml	Not stated
Analytical Sensitivity	≤0.1ng/ml	0.02ng/ml
Analytical Specificity	25 potential cross-reactants tested. <1% cross reactivity observed at the concentrations stated in the pack leaflet (dependent on cross-reactant).	12 potential cross-reactants tested at 40ng/mL. Cross-reactivity ranged from 0-10.4%.
Interfering Substances	<15% interference at: Bilirubin – 20mg/ dL Haemoglobin – 750mg/dL Protein –10g/dL Triglycerides – 500mg/dL SHBG – 90nmol/L Not listed Not listed	No interference at: Bilirubin – 25mg/dL Haemoglobin – 1.0g/dL Not listed Not listed Not listed Lipemia – 1500mg/dL Biotin – 30ng/mL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 29 2004

Ms. Susan Leonard
Regulatory Affairs Manager
Axis-Shield Diagnostics Ltd.
The Technology Park
Dundee, Scotland
United Kingdom DD2 1XA

Re: k041866
Trade/Device Name: Abbott AxSYM® Testosterone Microparticle Enzyme Immunoassay (MEIA)
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIS, CDZ
Dated: July 7, 2004
Received: July 9, 2004

Dear Ms. Leonard:

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,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

AUG 0 9 2004

Revised

Indications for Use

510(k) Number (if known): K041866

Device Name: Abbott AxSYM® Testosterone Microparticle Enzyme Immunoassay (MEIA)

Indications For Use:

AxSYM® Testosterone is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative determination of testosterone in human serum and plasma on the AxSYM System.

Testosterone monitoring is used clinically to diagnose and differentiate endocrine disorders. In males, these include hypogonadism, testicular failure, infertility, hypopituitarism and hyperprolactinemia. In females, polycystic ovary syndrome, adrenal hyperplasia, infertility, hirsutism, amenorrhea, obesity and virilization can cause changes in serum testosterone levels.

The AxSYM® Testosterone assay is used as an aid in the investigation of infertility in males and of hirsutism and virilization in females.

The AxSYM® Testosterone Standard Calibrators are for the standard calibration of the AxSYM system when used for the quantitative determination of testosterone in human serum and plasma.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041866