K040761

APR 3 0 2004

510(k) Summary of Safety and Effectiveness for Abbott AxSYM® Cyclosporine

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990 and 21 CFR 807.92

Submitter's Name:	Abbott Laboratories Diagnostic Division 100 Abbott Park Road Abbott Park, IL 60064-3537
Contact:	Grace LeMieux Phone: (847) 937-0165 Fax: (847) 937-9616
Common Name:	Cyclosporine
Trade Name:	AxSYM® Cyclosporine
FDA Classification:	Sec.862.1235 Cyclosporine test system. Class II (special control)
Predicate Device:	Abbott TDx®/TDxFLx® Cyclosporine Monoclonal Whole Blood

Device Description:
The AxSYM Cyclosporine assay requires the use of the AxSYM System, a random and continuous access immunoassay analyzer. The analyzer performs all sample and reagent transfers, incubations, and data processing, and completes the assay with a printed report. Samples (calibrators, controls, and specimens) are pretreated to minimize interference from endogenous protein-bound fluorescent compounds. Sample pretreatment consists of lysing the erythrocytes in the whole blood with Solubilization Reagent and precipitating protein with Precipitation Reagent. Cyclopsorine is dissolved into the liquid phase. The mixture is centrifuged to generate a clarified extract. The AxSYM Cyclopsorine assay is performed on the clarified extract. The AxSYM Cyclosporine Reagents and pretreated sample are pipetted in the following sequence:

- Pretreated sample, Cyclosporine Antibody, Cyclosporine Pretreatment and Solution 4 (Line Diluent) required for one test are pipetted by the Sample Probe into one well of a Reaction Vesssel (RV) to form a Sample Solution.
- Cyclosporine Fluorescein Tracer is added to a second well of the RV.
- The RV is immediately transferred into the Processing Center. Further pipetting is done in the Processing Center by the Processing Probe.

- Aliquots of Solution 4 and Sample Solution are dispensed into the RV curvette.
- The polarized fluorescent background is measured by the FPIA optical assembly.
- Second aliquots of Solution 4 and Sample Solution, and an aliquot of Cyclosporine Fluorescein Tracer are dispensed into the same RV curvette.
- The intensity of polarized fluorescent light is measured by the FPIA optical assembly.

Intended Use:
The Abbott AxSYM® Cyclosporine assay is a Fluorescence Polarization Immunoassay (FPIA) *in vitro* reagent system for the quantitative measurement of cyclosporine (cyclosporine A) in human whole blood as an aid in the management of cardiac, liver, and renal transplant patients.

Comparison to Predicate Device:

The Abbott AxSYM Cyclosporine assay is substantially equivalent to Abbott TDx/TDxFLx Cyclosporine Monoclonal Whole Blood in that:

1. Both assays utilize Fluorescence Polarization Immunoassay (FPIA) technology.
2. Both are intended for use in quantitative measurement of cyclosporine (cyclosporine A) in human whole blood as an aid in the management of cardiac, liver, and renal transplant patients.
3. Both assays use mouse monoclonal antibody
4. Both assays require pretreatment of samples (calibrators, controls and patient samples) with solubilization reagent and whole blood precipitation reagent before testing.
5. Both assays utilize cyclosporine monoclonal whole blood fluorescein tracer.

The Abbott AxSYM Cyclosporine and Abbott TDx/TDxFLx Cyclosporine Monoclonal Whole Blood Differ in that:

1. The AxSYM Cyclosporine Calibrators range is 0 ng/mL to 800 ng/mL and TD/TDxFLx Cyclosporine Calibrators range is 0 ng/mL to 1500 ng/mL.
2. The AxSYM Cyclosporine assay is used on the AxSYM instrument platform and the TDx/TDxFLx Cyclosporine Monocloncal Whole Blood assay is used on the TDx/TDxFLx instrument.

Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination:

A comparison study was performed between the AxSYM Cyclosporine and TDx/TDxFLx Cyclosporine Monoclonal Whole Blood assay using 754 specimens (Heart = 194, Kidney = 330, Liver = 230: Total 754). A Passing Bablok linear regression analysis yields a Spearman correlation coefficient of 0.974, a slope of 0.81 (95% confidence interval of 0.80 to 0.82) and a y-axis intercept of -4.95 ng/mL (95% confidence interval of –8.11 to –2.12).

Conclusion:

The Abbott AxSYM Cyclosporine assay is substantially equivalent to Abbott TDx/TDxFLx Cyclosporine Monoclonal Whole Blood, approved under the premarket application P890025/S010.

Prepared and submitted by:

Abbott Laboratories
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

APR 3 0 2004

Ms. Grace LeMieux
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Abbott Laboratories
Diagnostic Division
100 Abbott Park Road
Abbott Park, IL 60064

Re: k040761
Trade/Device Name: Abbott AxSYM® Cyclosporine
Regulation Number: 21 CFR 862.1235
Regulation Name: Cyclosporine test system
Regulatory Class: Class II
Product Code: MKW
Dated: March 24, 2004
Received: March 25, 2004

Dear Ms. LeMieux:

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

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Indication For Use Statement

Device Name: Abbott AxSYM® Cyclosporine

Indication for Use:

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(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 _____

(Optional format 1-2-96)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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