MAR 1 3 2002

510(k) Summary

K012998

Submitter's Name/Address
Abbott Laboratories
1920 Hurd Drive MS 8-21
Irving, Texas 75038

Contact Person
Alicia Simpson
Senior Regulatory Affairs Specialist
Regulatory Affairs
(972) 518-7864
Fax (972) 518-6533

Date of Preparation of this Summary: November 21, 2001

Device Trade or Proprietary Name: Amphetamine/Methamphetamine

Device Common/Usual Name or Classification Name: Amphetamine/Methamphetamine

Classification Number/Class: LAF/Class II

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

The assigned 510(k) number is: K012998.

Test Description:

Amphetamine/Methamphetamine is an in vitro diagnostic assay for the qualitative analysis of amphetamine/methamphetamine in human urine. The assay is a homogeneous enzyme immunoassay with a 1,000 ng/mL cutoff. The assay is based on competition between drug in the specimen and drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for antibody binding sites. Enzyme activity decreases upon binding to the antibody, so the drug concentration in the specimen can be measured in terms of enzyme activity.

Substantial Equivalence:

The Amphetamine/Methamphetamine assay is substantially equivalent to the Emit® II Monoclonal Amphetamine/Methamphetamine assay (K920507) on the SYVA®-30R Analyzer.

Both assays yield similar Performance Characteristics.

Similarities:

- Both assays are in vitro immunoassays.
- Both assays can be used for the qualitative analysis of amphetamine/methamphetamine.
- Both assays yield similar results.
- Both assays are based on the competition between drug in the specimen and drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for antibody binding sites.

Differences:

- Amphetamine/Methamphetamine is a qualitative assay. Emit II is a qualitative and semiquantitative assay.

Intended Use:

The Amphetamine/Methamphetamine assay is used for the qualitative analysis of amphetamine/ methamphetamine in human urine with a cutoff of 1,000 ng/mL. For use in clinical laboratories.

The Amphetamine/Methamphetamine assay is calibrated with d-methamphetamine and will detect a variety of amphetamines and their metabolites.

Performance Characteristics:

Comparative performance studies were conducted using the AEROSET® System. The Amphetamine/Methamphetamine assay method comparison yielded acceptable correlation with the Emit II Monoclonal Amphetamine/Methamphetamine assay on the SYVA-30R Analyzer. The concordance table shows 100% agreement. The Amphetamine/Methamphetamine assay method comparison yielded acceptable correlation with GC/MS. The concordance table shows 81% agreement with GC/MS. The clinical specimens tested ranged from 826 to 1,994 ng/mL. Precision studies were conducted using the Amphetamine/Methamphetamine assay. A within-run and total precision study was performed using five levels of control material. The total %CV for Verifier I is 0.42%, Cutoff Calibrator is 0.40%, Verifier II is 0.39%, – 25% Control of Cutoff Calibrator is 0.44%, and + 25% Control of Cutoff Calibrator is 0.41%. The Amphetamine/Methamphetamine assay cutoff is 1,000 ng/mL. The limit of detection (sensitivity) of the Amphetamine/Methamphetamine assay is 500 ng/mL.

These data demonstrate that the performance of the Amphetamine/Methamphetamine assay is substantially equivalent to the performance of the Emit II Monoclonal Amphetamine/Methamphetamine assay on the SYVA-30R Analyzer.

Conclusion:

The Amphetamine/Methamphetamine assay is substantially equivalent to the Emit II Monoclonal Amphetamine/Methamphetamine assay on the SYVA-30R Analyzer as demonstrated by results obtained in the studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 3 2002

Ms. Alicia Simpson
Senior Regulatory Affairs Specialist
Abbott Laboratories
1920 Hurd Drive 8-21
Irving, TX 75038

Re: k012998
Trade/Device Name: Amphetamine/Methamphetamine
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ
Dated: November 26, 2001
Received: November 28, 2001

Dear Ms. Simpson:

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 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 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

510(k) Number (if known): K012998

Device Name: Amphetamine/Methamphetamine

Indications For Use:

The Amphetamine/Methamphetamine assay is used for the qualitative analysis of amphetamine/methamphetamine in human urine with a cutoff of 1,000 ng/mL for use in clinical laboratories. Measurements obtained by this device are used in the diagnosis and treatment of amphetamine/methamphetamine use or overdose.

The Amphetamine/Methamphetamine assay is calibrated with d-methamphetamine and will detect a variety of amphetamines and their metabolites.

The Amphetamine/Methamphetamine assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

(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)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012998