MAR 2 0 2002

K012996

510(k) Summary

Submitter's Name/Address
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Date of Preparation of this Summary:	November 21, 2001
Device Trade or Proprietary Name:	Barbiturates
Device Common/Usual Name or Classification Name:	Barbiturates
Classification Number/Class:	KLT/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: K012996.

Test Description:

Barbiturates is an in vitro diagnostic assay for the qualitative analysis of barbiturates in human urine. The assay is a homogeneous enzyme immunoassay with a 200 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. Active enzyme converts NAD to NADH, resulting in an absorbance change that can be measured spectrophotometrically.

Substantial Equivalence:

The Barbiturates assay is substantially equivalent to the Emit® II Barbiturate assay (K902580) 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 barbiturates.
- 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:

- There is a difference between the assay ranges.
- Barbiturates is a qualitative assay. Emit II is a qualitative and semiquantitative assay.

Intended Use:

The Barbiturates assay is used for the qualitative analysis of barbiturates in human urine with a cutoff of 200 ng/mL. For use in clinical laboratories.

The Barbiturates assay is calibrated with secobarbital and will detect a variety of Barbiturates.

Performance Characteristics:

Comparative performance studies were conducted using the AEROSET® System. The Barbiturates assay method comparison yielded acceptable correlation with the Emit II Barbiturate assay on the SYVA-30R Analyzer. The concordance table for the Barbiturates assay shows 96% agreement. Six samples were negative using the Emit II Barbiturate assay on the SYVA-30R Analyzer and positive using the Barbiturates assay. These samples were shown to contain 829, 898, 661, 998, 1,048 and 969 ng/mL of phenobarbital as determined by GC/MS. The Barbiturates assay method comparison yielded acceptable correlation with GC/MS. The concordance table for the Barbiturates assay shows 100%

agreement with GC/MS. The clinical specimens tested ranged from 302 to 6,481 ng/mL. Precision studies were conducted using the Barbiturates assay. A within-run and total precision study was performed using five levels of control material. The total %CV for Verifier I is 0.47%. The total %CV for the Cutoff Calibrator is 0.53%. The total %CV for Verifier II is 0.55%. The total %CV for the - 25% Control of Cutoff Calibrator and the + 25% Control of Cutoff Calibrator samples are 0.61% and 0.55%, respectively. The Barbiturates assay cutoff is 200 ng/mL. The limit of detection (sensitivity) of the Barbiturates assay is 20 ng/mL. These data demonstrate that the performance of the Barbiturates assay is substantially equivalent to the performance of the Emit II Barbiturate assay on the SYVA 30R Analyzer.

Conclusion:

The Barbiturates assay is substantially equivalent to the Emit II Barbiturate 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 2 0 2002

Ms. Linda Morris
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Re: k012996
Trade/Device Name: Barbiturates
Regulation Number: 21 CFR 862.3150
Regulation Name: Batbiturate test system
Regulatory Class: Class II
Product Code: DIS
Dated: November 26, 2001
Received: November 28, 2001

Dear Ms. Morris:

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): K012996

Device Name: Barbiturates

Indications For Use:

The Barbiturates assay is used for the qualitative analysis of barbiturates in human urine with a cutoff of 200 ng/mL for use in clinical laboratories. Measurements obtained by this device are used in the diagnosis and treatment of barbiturates use or overdose.

The Barbiturates assay is calibrated with secobarbital and will detect a variety of Barbiturates.

The Barbiturates 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
510(k) Number K012996