510(k) Summary

MAR 2 0 2002

K013100

Submitter's Name/Address
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Date of Preparation of this Summary:	November 21, 2001
Device Trade or Proprietary Name:	Propoxyphene
Device Common/Usual Name or Classification Name:	Propoxyphene
Classification Number/Class:	JXN/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: K013100.

Test Description:

Propoxyphene is an in vitro diagnostic assay for the qualitative analysis of Propoxyphene in human urine. The assay is a homogeneous enzyme immunoassay with a 300 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.

The Propoxyphene assay is substantially equivalent to the Emit® II Propoxyphene assay (K923873) 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 Propoxyphene.
- 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.
- Both assays have the same assay ranges (cutoff).

Differences:

- The Propoxyphene assay is qualitative. The Emit II Propoxyphene assay is qualitative and semiquantitative.

Intended Use:

The Propoxyphene assay is used for the qualitative analysis of propoxyphene in human urine with a cutoff of 300 ng/mL. For use in clinical laboratories.

The Propoxyphene assay is calibrated with propoxyphene and will detect propoxyphene and its metabolites and analogs.

Performance Characteristics:

Comparative performance studies were conducted using the AEROSET® System. The Propoxyphene assay method comparison yielded acceptable correlation with the Emit II Propoxyphene assay on the SYVA-30R Analyzer. The concordance table for the Propoxyphene assay shows 99% agreement. One sample was positive using the Emit II Propoxyphene assay on the SYVA-30R Analyzer and negative using the Propoxyphene assay on the AEROSET System. This sample was shown to contain 404 ng/mL of norpropoxyphene determined by GC/MS. The Propoxyphene assay method comparison yielded

agreement with GC/MS. The clinical specimens tested ranged from 404 to 56,662 ng/mL. Precision studies were conducted using the Propoxyphene assay. The total %CV for Verifier I is 1.25%. The total %CV for the Cutoff Calibrator is 1.49%. The total %CV for Verifier II is 1.19%. The total %CV for the - 25% Control of Cutoff Calibrator and the + 25% Control of Cutoff Calibrator samples are 2.39% and 1.90%, respectively. The Propoxyphene assay cutoff is 300 ng/mL. The limit of detection (sensitivity) of the Propoxyphene assay is 60 ng/mL. These data demonstrate that the performance of the Propoxyphene assay is substantially equivalent to the performance of the Emit II Propoxyphene assay on the SYVA-30R Analyzer.

Conclusion:

The Propoxyphene assay is substantially equivalent to the Emit II Propoxyphene 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
Senior Regulatory Affairs Specialist
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1921 Hurd Dr.
Irving. Texas 75038

Re: k013100
Trade/Device Name: Propoxyhene
Regulation Number: 21 CFR 862.3700
Regulation Name: Propoxyphene test system
Regulatory Class: Class II
Product Code: JXN
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): K013100

Device Name: Propoxyphene

Indications For Use:

The Propoxyphene assay is used for the qualitative analysis of propoxyphene in human urin with a cutoff of 300 ng/mL for use in clinical laboratories. Measurements obtained by this device are used in the diagnosis and treatment of propoxyphene use or overdose.

The Propoxyphene assay is calibrated with propoxyphene and will detect propoxyphene an metabolites and analogs.

The Propoxyphene 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. Ga chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinic 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 NEE

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 K013100