DEC 1 4 2001

510(k) Summary

Submitter's Name/Address
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Contact Person
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Regulatory Affairs
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Date of Preparation of this Summary:	October 23, 2001
Device Trade or Proprietary Name:	Ethanol
Device Common/Usual Name or Classification Name:	Ethyl Alcohol
Classification Number/Class:	DML/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: K013538.

Test Description:

Ethanol is an in vitro diagnostic assay for the quantitative analysis of ethyl alcohol (ethanol) in human serum, plasma, or urine. The assay is based on an enzymatic reaction. Active enzyme converts NAD to NADH, resulting in an absorbance change that can be measured spectrophotometrically. The increase in absorbance at 340 nm is proportional to the concentration of alcohol in the specimen.

Substantial Equivalence:

The Ethanol assay is substantially equivalent to the Emit® II Plus Ethyl Alcohol assay (K993980) 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 quantitative analysis of ethyl alcohol.
- Both assays yield similar results.
- Both assays are based on an enzymatic reaction.

Differences:

- There is no difference.

Intended Use:

The Ethanol assay is used for the quantitative analysis of ethyl alcohol (ethanol) in human serum, plasma, or urine.

Performance Characteristics:

Comparative performance studies were conducted using the AEROSET® System. The Ethanol assay method comparison yielded acceptable correlation with the Emit® II Plus Ethyl Alcohol assay on the SYVA 30R Analyzer. For serum, the correlation coefficient = 0.996, slope = 1.00, and the Y-intercept = -1.87 mg/dL. For urine the correlation coefficient = 0.997, slope = 1.01, and the Y-intercept = -4.85 mg/dL. Precision studies were conducted using the Ethanol assay. A within-run study was performed using three levels of control material. The total %CV for the low control is 5.1%, 100 mg/dL calibrator/control is 2.8%, and the high control is 1.7 %. The Ethanol assay range is 10 to 600 mg/dL. The limit of quantitation (sensitivity) of the Ethanol assay is 5 mg/dL. These data demonstrate that the performance of the Ethanol assay is substantially equivalent to the performance of the Emit II Plus Ethyl Alcohol assay on the SYVA-30R Analyzer.

Conclusion:

The Ethanol assay is substantially equivalent to the Emit II Plus Ethyl Alcohol assay on the SYVA-30R Analyzer as demonstrated by results obtained in the studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Alicia Simpson
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Irving, TX 75038

DEC 1 4 2001

Re: k013538
Trade/Device Name: Ethanol
Regulation Number: 21 CFR 862.3040
Regulation Name: Alcohol Test System
Regulatory Class: Class II
Product Code: DML
Dated: October 23, 2001
Received: October 24, 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): K013538

Device Name: Ethanol

Indications For Use:

The Ethanol assay is used for the quantitative analysis of ethyl alcohol (ethanol) in human serum, plasma, or urine. The Ethanol assay should be exclusively used to detect ethanol and not other alcohols such as isopropanol or methanol. Reactivity with compounds structurally unrelated to ethanol has not been observed.

Thomas C. Frost for Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number 1401 3538

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)