

JUL 22 1998

## 510(k) Summary

1698 1920

**Submitter's Name/Address**

Abbott Laboratories  
1920 Hurd Drive  
Irving, Texas 75038

**Contact Person**

Mark Littlefield  
Section Manager MS 1-8  
Regulatory Affairs  
(972) 518-6062  
Fax (972) 753-3367

**Date of Preparation of this Summary:**

May 29, 1998

**Device Trade or Proprietary Name:**

Amm

**Device Common/Usual Name or Classification Name:** Ammonia

**Classification Number/Class:**

75JIX/Class I

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: \_\_\_\_\_.

**Test Description:**

Ammonia is an *in vitro* diagnostic assay for the quantitative determination of ammonia in human plasma. The Ammonia assay is a clinical chemistry assay which utilizes the amination of  $\alpha$ -ketoglutarate by ammonia ( $\text{NH}_3$ ) along with the concomitant oxidation of  $\text{NH}_x\text{DPH}$ . These reactions, catalyzed by glutamate dehydrogenase (GLDH), produce glutamate and  $\text{NH}_x\text{DP}^+$ . The oxidation of  $\text{NH}_x\text{DPH}$  produces a decrease in absorbance at 340 nm which is directly proportional to the concentration of ammonia in the sample.

**Substantial Equivalence:**

The Ammonia assay is substantially equivalent to the A-GENT<sup>®</sup> Ammonia assay (K870787) on the ABBOTT SPECTRUM<sup>®</sup> Series II<sup>™</sup> System.

Both assays yield similar Performance Characteristics.

**Similarities:**

- Both assays are *in vitro* clinical chemistry methods.
- Both assays can be used for the quantitative determination of ammonia.
- Both assays yield similar clinical results.

**Intended Use:**

The Ammonia assay is used for the quantitation of ammonia in human plasma.

**Performance Characteristics:**

Comparative performance studies were conducted using the AEROSSET™ System. The Ammonia assay method comparison yielded acceptable correlation with the A-GENT Ammonia assay on the ABBOTT SPECTRUM Series II System. The correlation coefficient = 0.9957, slope = 0.971, and Y-intercept = -2.083 μmol/L. Precision studies were conducted using the Ammonia assay. Within-run, between-run, and between-day studies were performed using three levels of control material. The total %CV for Level 1/Panel 103 is 11.7%, 4.0% for Level 2/Panel 104, and 5.5% for Level 3/Panel 105. The Ammonia assay is linear up to 1,574.9 μmol/L. The limit of quantitation (sensitivity) of the Ammonia assay is 20.6 μmol/L. These data demonstrate that the performance of the Ammonia assay is substantially equivalent to the performance of the A-GENT Ammonia assay on the ABBOTT SPECTRUM Series II System.

**Conclusion:**

The Ammonia assay is substantially equivalent to the A-GENT Ammonia assay on the ABBOTT SPECTRUM Series II System 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

JUL 22 1998

Anna G. Bentley  
Director, Regulatory and Quality Affairs  
EM Science  
480 S. Democrat Road  
Gibbstown, New Jersey 08027

Re: K981926  
Ethyl Alcohol Calibrators  
Regulatory Class: II  
Product Code: DLJ  
Dated: June 1, 1998  
Received: June 2, 1998

Dear Ms. Bentley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

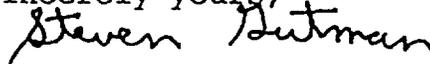
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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

0(k) Number (if Known): K 981926

Device Name: Ethyl Alcohol Clinical Standard Solutions

Indications for Use:

The Ethyl Alcohol Clinical Standard Solutions are intended for use in the calibration and standardization of instruments and methods for the determination of ethyl alcohol in whole blood or serum. The Standard Solutions may also be used for validation of the laboratory's routine standards and/or control materials.

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

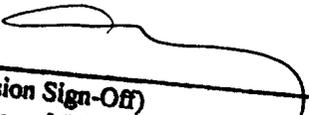
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K 981926