K972011

JUL 22 1997

510(k) Summary for OPUS Ethanol

1. Manufactures Name, Address, Telephone, and contact person, date of preparation:

Manufacturer:	Behring Diagnostics Inc. 151 University Avenue Westwood, MA 02090 617-320-3117 Attn.: Ruth Forstadt
Preparation date:	May 29, 1997

2. Device Name/ Classification:

OPUS Ethanol:	Alcohol Test System
Classification Number:	Class II (862.3040)

3. Identification of the legally marketed device:

Abbott TDx/TDxFLx REA Ethanol assay (K871645).

4. Device Description:

OPUS Ethanol is a set of *in vitro* diagnostic reagents intended to be used together with the OPUS immunoassay analyzers for the quantitative measurement of ethanol in human serum or plasma. Assay range is 10-300 mg/dl.

5. Device Intended Use:

OPUS Ethanol is an *in vitro* diagnostic thin film-based, fluorescence inhibition test for the quantitative measurement of ethanol in human serum or plasma as an aid in the diagnosis and treatment of alcohol intoxication and poisoning. OPUS Ethanol is intended for use with the OPUS analyzers.

6. Medical device to which equivalence is claimed and comparison information:

The OPUS Ethanol assay is substantially equivalent in intended use to results obtained using the Abbott TDx/TDxFlx REA Ethanol assay. The Abbott TDx/TDxFlx REA Ethanol assay, like the proposed product, are based on a six level calibrator system. Both use the enzymes alcohol dehydrogenase and diaphorase to produce a formazan dye.

The OPUS Ethanol differs from the Abbott TDx/TDxFlx REA Ethanol assay in the technologies used. In the Abbott TDx/TDxFlx REA Ethanol assay, an REA method is used, while a thin film-based fluorescence inhibition technology is used in the OPUS Ethanol test. Human whole blood, serum, plasma or urine can be tested with the Abbott TDx/TDxFlx REA Ethanol assay, but only human serum or plasma in the OPUS Ethanol test. Also, the Abbott TDx/TDxFlx REA Ethanol include tri-level controls for whole blood and serum, whereas the OPUS Ethanol test does not include controls. Additionally, because of the volatile nature of ethanol, the Abbott TDx/TDxFlx REA Ethanol assay, in its liquid format, can run no more than 12 samples at a time, while the OPUS Ethanol assay because of its solid format, is not limited in this way by sample volatility.

7. Device Performance Characteristics:

Precision

Intra-assay precision was determined by the evaluation of three levels of control material in replicates of twenty (20) each. %CV ranged from 5.1% to 8.7%.

Inter-assay precision was determined by the evaluation of three levels of control material in duplicate, assayed over a five day period to total 20 replicates. %CV ranged from 4.97% to 8.73%.

Accuracy by Recovery

Recovery was determined by making four dilutions of an elevated Bone AP patient sample into a normal human serum pool. The samples were assayed using OPUS Ethanol in duplicate. Percent recovery ranged from 92% to 113%

Accuracy by Correlation

OPUS Ethanol was compared to a commercially available immunoassay by evaluation of 50 serum samples ranging from 24.65 to 278.50 mg/dl. A correlation coefficient of 0.995 was obtained with a y-intercept value of 5.05 and a slope of 0.89.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ruth Forstadt
Regulatory Affairs Associate
Behring Diagnostics
151 University Avenue
Westwood, Massachusetts 02090

JUL 22 1997

Re: K972011
OPUS® Ethanol Test System
Regulatory Class: II
Product Code: DIC
Dated: May 29, 1997
Received: May 30, 1997

Dear Ms. Forstadt:

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 requirement, 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.

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 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):_____

Device Name: OPUS Ethanol Test System

Indications For Use:

OPUS Ethanol is an *in vitro* diagnostic thin film-based, fluorescence inhibition test for the quantitative measurement of ethanol in human serum or plasma as an aid in the diagnosis and treatment of alcohol intoxication and poisoning. OPUS Ethanol is intended for use with the OPUS analyzers.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K970114

(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)

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