

AUG 25 1998

DADE BEHRING INC.  
P.O. Box 6101  
Newark, DE 19714

DADE BEHRING

K98280

**Summary of Safety and Effectiveness Information**

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.

**Submitter's Name:** Rebecca S. Ayash  
Dade Behring Inc.  
Building 500, Mailbox 514  
P.O. Box 6101  
Newark, DE 19714-6101

**Date of Preparation:** 8/13/98

**Device Name:** Valproic Acid Method

**Classification Name:** Enzyme Immunoassay, Valproic Acid

**Predicate Device:** Abbott AxSYM® Valproic Acid Assay

**Device Description:** The VALP method for the Dimension® clinical chemistry system is a particle enhanced turbidimetric inhibition immunoassay which uses a latex particle-valproic acid conjugate and valproic-acid specific monoclonal antibody (Ab). Valproic acid present in the sample competes with the particles for the antibody, thereby decreasing the rate of aggregation. The rate of aggregation is inversely proportional to the concentration of valproic acid in the sample. The rate of aggregation is measured using bichromatic turbidimetric readings at 340nm and 700nm



**Intended Use:** The VALP method for the Dimension® clinical chemistry system is a device used to quantitatively measure valproic acid, an anti-convulsant drug, in serum or plasma. VALP test results may be used in the diagnosis and treatment of valproic acid overdose and in monitoring levels of valproic acid to ensure appropriate therapy.

**Comparison to Predicate  
Device:**

Item	Dimension® VALP Method	Abbott AxSYM® Valproic Acid
Technology	Particle Enhanced Turbidimetric Inhibition Immunoassay	Fluorescence Polarization Immunoassay
Detection	Rate turbidimetric absorption	Fluorometric endpoint measurement
Sample Size	3µL	150µL
Sample Type	Serum or plasma	serum or plasma
Intended Use	For the quantitative measurement of valproic acid	For the quantitative measurement of valproic acid

**Comments on Substantial**

**Equivalence:** Split sample comparison between the VALP method for the Dimension® system and the Abbott AxSYM® Valproic Acid assay gave a correlation coefficient of 0.995, slope of 1.10, and an intercept of -2.82 µg/mL when tested with 158 clinical patient samples ranging from 11 - 147.7 µg/mL.

**Conclusion:** The VALP Method for the Dimension® clinical chemistry system is substantially equivalent in principle and performance to the Abbott AxSYM® Valproic Acid Assay based on the split sample comparison summarized above.



Rebecca S. Ayash  
Regulatory Affairs and  
Compliance Manager  
Date: 8/13/98

AUG 25 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Rebecca S. Ayash  
Regulatory Affairs and Compliance Manger  
Dade Behring, Inc.  
Building 500, Mailbox 514  
P.O. Box 6101  
Newark, Delaware 19714-6101

Re: K982880  
Valproic Acid Method  
Regulatory Class: II  
Product Code: LEG  
Dated: August 13, 1998  
Received: August 14, 1998

Dear Ms. Ayash:

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 (Pre-market 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 pre-market 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.

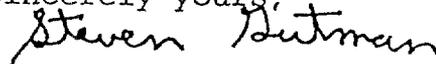
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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

### Indications Statement

**Device Name:** Valproic Acid (VALP) Method

**Indications for Use:** The VALP method for the Dimension® RxL clinical chemistry system is a device used to measure valproic acid, an anti-convulsant drug, in serum or plasma. VALP test results may be used in the diagnosis and treatment of valproic acid overdose and in monitoring levels of valproic acid to ensure appropriate therapy.

*Rebecca S. Ayash*

Rebecca S. Ayash  
Regulatory Affairs and  
Compliance Manager  
Date: 8/13/98

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

K982880  
510(k) Number

*[Signature]*  
Division Sign-Off  
Office of Device Evaluation

*von R. Montgomery*

Prescription Use   
(Per 21 CFR 801.109)

Over-The-Counter Use