AUG 25 1998

DADE BEHRING

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

K982880

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
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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

$$\text{Valproic acid} + \text{PR} + \text{Ab} \longrightarrow \text{PR-Ab complex} + \text{Valproic acid -Ab}$$
(scatters light at 340nm)

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 25 1998

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 (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.

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

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K982880
510(k) Number

Division Sign-Off
Office of Device Evaluation

Prescription Use ✓
(Per 21 CFR 801.109)

Over-The-Counter Use ____