

MAY - 8 1998

**BECKMAN**

K981403

**Summary of Safety & Effectiveness  
IMMAGE® Immunochemistry System Valproic Acid (VPA) Reagent**

**1.0 Submitted By:**

Annette Hellie  
Sr. Regulatory Specialist, Product Submissions  
Beckman Coulter, Inc.  
200 S. Kraemer Blvd., W-104  
Brea, California 92822-8000  
Telephone: (714) 993-8767  
FAX: (714) 961-4123

**2.0 Date Submitted:**

April 16, 1998

**3.0 Device Name(s):****3.1 Proprietary Names**

IMMAGE® Immunochemistry System Valproic Acid (VPA) Reagent  
IMMAGE® Immunochemistry System Drug Calibrator 1

**3.2 Classification Name**

Valproic Acid (Not classified)  
Calibrator (21 CFR §862.3200)

**4.0 Predicate Device(s):**

IMMAGE System Reagent	Predicate	Manufacturer	Docket Number
IMMAGE System Valproic Acid (VPA)	TDx®** Valproic Acid (VPA)	Abbott* Laboratories, Inc	K941615

\*Abbott Laboratories, Abbott Park, IL 60064

\*\*Trademark of Abbott Laboratories

**5.0 Description:**

The IMMAGE Immunochemistry System VPA Reagent in conjunction with Beckman Drug Calibrator 1, is intended for use in the quantitative determination of valproic acid in human serum or plasma on Beckman Coulter's IMMAGE Immunochemistry Systems.

**6.0 Intended Use:**

The IMAGE® Immunochemistry System Valproic Acid (VPA) Reagent, when used in conjunction with Beckman IMAGE® Immunochemistry Systems and Beckman Drug Calibrator 1, is intended for the quantitative determination of valproic acid in human serum or plasma by rate nephelometric inhibition immunoassay.

The IMAGE® Immunochemistry Systems Drug Calibrator 1, used in conjunction with IMAGE reagents, is intended for use on Beckman's IMAGE Immunochemistry Systems for the calibration of Carbamazepine, Phenobarbital, Phenytoin, Theophylline, and Valproic Acid test systems.

**7.0 Comparison to Predicate(s):**

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

SIMILARITIES		
IMAGE System VPA Reagent	Intended use.	Same as Abbott TDx Valproic Acid Reagent
	Liquid stable reagents.	
	Initial analytic ranges.	
DIFFERENCES		
IMAGE System VPA Reagent	IMAGE utilizes nephelometric inhibition immunoassay	Abbott TDx reagents utilize fluorescence polarization immunoassay
	Antibody source for IMAGE VPA is goat.	Antisera source for TDx valproic Acid is sheep.
	Calibration	IMAGE VPA uses a single point calibration while TDx is multipoint.

**8.0 Summary of Performance Data:**

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, stability, and imprecision experiments.

**Method Comparison Study Results**  
 IMAGE Valproic Acid (VPA) Reagent

Analyte	Sample Type	Slope	Intercept	r	n	Predicate Method
IMAGE VPA Reagent	serum	0.971	2.62	0.997	129	Abbott TDx Valproic Acid

**Estimated Imprecision**

Sample	Mean (µg/mL)	S.D. (µg/mL)	%C.V.	N
Within-Run Imprecision				
Level 1	47.5	0.99	2.1	80
Level 2	91.3	1.54	1.7	80
Level 3	137	2.5	1.8	80

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

MAY - 8 1998

Annette Hellie  
Senior Regulatory Specialist  
Beckman Coulter, Inc.  
200 S. Kraemer Boulevard, W-337  
P.O. Box 8000  
Brea, California 92822-8000

Re: K981403  
IMMAGE® System Valproic Acid (VPA) Reagent  
Regulatory Class: II  
Product Code: DKB  
Dated: April 16, 1998  
Received: April 17, 1998

Dear Ms. Hellie:

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.

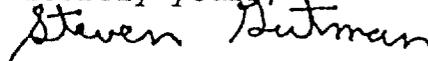
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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

510(k) Number (if known): K981403

Device Name: **IMMAGE® Immunochemistry System  
Valproic Acid (VPA) Reagent**

Indications for Use:

**The IMMAGE Immunochemistry System Valproic Acid (VPA) Reagent, when used in conjunction with Beckman IMMAGE™ Immunochemistry Systems and Beckman Drug Calibrator 1, is intended for the quantitative determination of valproic acid in human serum or plasma by rate nephelometric inhibition immunoassay.**

**Clinical Significance:**

**Valproic acid is an anti-convulsant indicated for use as sole and adjunctive therapy in the treatment of petit mal and multiple seizure types, which include complex absence seizures. The test is used to monitor the level of valproic acid in the blood to ensure that proper therapeutic levels are maintained and that the concentration remains below the level where hepatotoxicity may occur.**

(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)*

Prescription Use  (per 21 CFR 801.109)

OR

Over-the-Counter Use   
Optional Format 1-2-96

*Therese J. Valier for CW Montgomery*  
(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K981403