BECKMAN

Summary of Safety and Effectiveness
Beckman Instruments, Inc.
SYNCHRON Systems Valproic Acid (VPA) Reagent
Section 510(k) Notification

MAY 1 5 1996

K961256

1.0 **Submitted By:**

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2.0 **Date Submitted:**

March 29, 1996

3.0 **Device Name:**

3.1 Proprietary Names:

SYNCHRON® Systems Valproic Acid (VPA) Reagent

SYNCHRON® Systems Drug Calibrator 1

3.2 Classification Names:

Valproic Acid Test System (Not Classified)

Calibrator (21 CFR §862.1150)

4.0 **Predicate Devices:**

PREDICATE DEVICE SELECTION

SYNCHRON Systems Reagent	Predicate	Manufacturer	Docket Number
Valproic Acid Reagent	TDxFLx®** Valproic Acid Reagent	Abbott* Laboratories, Inc.	K904226

*Abbott Laboratories, Abbott Park, IL 60064
** Trademark of Abbott Laboratories, Inc.

5.0 **Description:**

The Beckman SYNCHRON Systems Valproic Acid (VPA) test system used in conjunction with the SYNCHRON Systems Drug Calibrator 1 is designed for optimal performance on the Beckman SYNCHRON family of clinical analyzers for the quantitative measurement of valproic acid in serum and plasma . The SYNCHRON family of clinical analyzers include the SYNCHRON CX®4, CX®4CE, CX4 DELTA, CX5, CX5CE, CX5 DELTA, CX7, and CX7 DELTA Systems.

6.0 **Intended Use:**

The SYNCHRON Systems Valproic Acid reagent in conjunction with the SYNCHRON Drug Calibrator 1 is intended for use in the quantitative determination of valproic acid in human serum and plasma. This assay is designed for use with the family of SYNCHRON System analyzers which include the SYNCHRON CX®4, CX®4CE, CX4 DELTA, CX5, CX5CE, CX5 DELTA, CX7, and CX7 DELTA Systems.

7.0 **Comparison to Predicate:**

Method Comparison

Analyte	Slope	Intercept	r	n	Predicate
Valproic Acid	1.0443	2.00	0.9857	104	Abbott TDxFLx Valproic Acid Reagent

8.0 **Precision:**

Valproic Acid (VPA) Imprecision Study Results
Within Run Imprecision

Sample	Mean (µg/mL)	S.D. (µg/mL)	%C.V.	N
Low	34.5	1.1	3.1	80
Mid-Range	83.3	1.6	2.0	80
High	131.3	3.1	2.4	80

Valproic Acid (VPA) Imprecision Study Results
Total Imprecision

Sample	Mean (µg/mL)	S.D. (µg/mL)	%C.V.	N
Low	34.5	1.6	4.6	80
Mid-Range	83.3	3.1	3.8	80
High	131.3	3.6	2.7	80

9.0 **Analytic Range:**

Analyte	Sample Type	Measuring Range (µg/mL)	Assessment
Valproic Acid	Serum/Plasma	10-150	Linear

10.0 **Summary of Stability Data:**

Reagent and Calibrator	Findings
Valproic Acid (VPA) Reagent Valproic Acid Calibrator (Drug Cal 1)	24 Months (Reagent) 24 Months (Calibrator)

This summary of safety and effectiveness is being submitted in compliance to the requirements of the Safe Medical Device Act and the implementing regulation 21 CFR §807.92.