K971333

MAY 23 1997

Summary of Safety & Effectiveness
SYNCHRON Systems Enzyme Reagents and Enzyme Validator

1.0 **Submitted By:**

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2.0 **Date Submitted:**

8 May 1997

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON® Systems Alkaline Phosphatase (ALP) Reagent

SYNCHRON® Systems Cholinesterase (CHE) Reagent

SYNCHRON® Systems γ-Glutamyl Transferase (GGT) Reagent

SYNCHRON® Systems Lactate Dehydrogenase (LD) Reagent

SYNCHRON® Enzyme Validator Set

3.2 **Classification Name**

Alkaline Phosphatase or isoenzymes test system (21 CFR § 862.1050)

Cholinesterase test system (21 CFR § 862.3240)

Gamma-glutamyl transpeptidase and isoenzymes test system (21 CFR § 862.1360)

Lactate Dehydrogenase test system (21 CFR § 862.1440)

Calibrator (21 CFR § 862.1150)

4.0 Predicate Device(s):

SYNCHRON Reagent	Predicate	Predicate Company	Docket Number
SYNCHRON Systems Alkaline Phosphatase (ALP) Reagent	SYNCHRON Systems Alkaline Phosphatase (ALP) Reagent	Beckman Instruments Inc.	K881498
SYNCHRON Systems Cholinesterase (CHE) Reagent	SYNCHRON Systems Cholinesterase (CHE) Reagent	Beckman Instruments Inc.	K893583
SYNCHRON Systems γ-Glutamyl Transferase (GGT) Reagent	SYNCHRON Systems γ-Glutamyl Transferase (GGT) Reagent	Beckman Instruments Inc.	K881498
SYNCHRON Systems Lactate Dehydrogenase (LD) Reagent	SYNCHRON Systems Lactate Dehydrogenase (LD) Reagent	Beckman Instruments Inc.	K881498
SYNCHRON Enzyme Validator Set	SYNCHRON Enzyme Validator Set	Beckman Instruments Inc.	K951964

5.0 Description:

The SYNCHRON Systems ALP, CHE, GGT, and LD Reagents are intended for use on Beckman's SYNCHRON Clinical Systems. These reagents may be used in conjunction with the SYNCHRON Enzyme Validator for assay values which are compatible with those from methods recommended by the International Federation of Clinical Chemistry (IFCC) or the German Society for Clinical Chemistry (Deutsche Gesellschaft fur Klinische Chemie, DGKCh).

6.0 Intended Use:

The SYNCHRON Systems Alkaline Phosphatase (ALP) Reagent, in conjunction with SYNCHRON Enzyme Validator Set, is intended for the quantitative determination of alkaline phosphatase activity in human serum or plasma on SYNCHRON Systems. Use of this product, in conjunction with the SYNCHRON Enzyme Validator Set, will result in assay values which are compatible with those from methods recommended by the International Federation of Clinical Chemistry (IFCC) or the German Society for Clinical Chemistry (Deutsche Gesellschaft fur Klinische Chemie, DGKCh).

The SYNCHRON Systems Cholinesterase (CHE) Reagent, in conjunction with SYNCHRON Enzyme Validator Set, is intended for the quantitative determination of pseudo-cholinesterase activity in human serum or plasma on SYNCHRON Systems. Use of this product, in conjunction with the SYNCHRON Enzyme Validator Set, will result in assay values which are compatible with those from methods recommended by the German Society for Clinical Chemistry (Deutsche Gesellschaft fur Klinische Chemie, DGKCh).

The SYNCHRON Systems γ-Glutamyl Transferase (GGT) Reagent, in conjunction with SYNCHRON Enzyme Validator Set, is intended for the quantitative determination of γ-glutamyl transferase activity in human serum or plasma on SYNCHRON Systems. Use of this product, in conjunction with the SYNCHRON Enzyme Validator Set, will result in assay values which are compatible with those from methods recommended by the International Federation of Clinical Chemistry (IFCC) and the German Society for Clinical Chemistry (Deutsche Gesellschaft fur Klinische Chemie, DGKCh).

The SYNCHRON Systems Lactate Dehydrogenase (LD) Reagent, in conjunction with SYNCHRON Enzyme Validator Set, is intended for the quantitative determination of lactate dehydrogenase activity in human serum or plasma on SYNCHRON Systems. Use of this product, in conjunction with the SYNCHRON Enzyme Validator Set, will result in assay values which are compatible with those from methods recommended by the International Federation of Clinical Chemistry (IFCC) and the German Society for Clinical Chemistry (Deutsche Gesellschaft fur Klinische Chemie, DGKCh).

The SYNCHRON Enzyme Validator Set, in conjunction with specified enzyme assays on Beckman SYNCHRON Systems, is intended to provide points of reference in the measurement of selected human enzymes. Use of this product will result in assay values which are compatible with those from methods recommended by the International Federation of Clinical Chemistry (IFCC) and the German Society for Clinical Chemistry (Deutsche Gesellschaft fur Klinische Chemie, DGKCh).

7.0 Comparison to Predicate(s):

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

SIMILARITIES to the PREDICATE

Reagent	Aspect/Characteristic	Comments
SYNCHRON Systems Enzyme Reagents (ALP, CHE, GGT, LD)	Intended use	Same as the predicates
	Chemical Reaction	Same principle as the predicates
	Reagent Formulation	Same formulations as the predicates
	Stability	Same as the predicates
	Interferences	Same as the predicates
	Anti-Coagulants	Same as the predicates
	Packaging	Same as the predicates
SYNCHRON Enzyme Validator Set	Intended use	Same as the predicate
	Formulation	Same formulation as predicate
	Stability	Same as the predicate
	Packaging	Same as the predicate

DIFFERENCES from the PREDICATE

Reagent	Aspect/Characteristic	Comments
SYNCHRON Systems reagents (ALP, CHE, GGT, LD,)	Calibration	ALP, CHE, GGT, LD are calibrated with Enzyme Validator product and the predicate reagents are not
	Standardization to IFCC/DGKCh methods	When ALP, CHE, GGT, LD reagents are calibrated with Enzyme Validator, the assay results are standardized to compatible IFCC/DGKCh methods while assay results from the predicate reagents are not
	Reference Ranges	ALP, CHE, GGT, and LD reference ranges may differ from the predicates
SYNCHRON Enzyme Validator Set	Value Assignment	SYNCHRON Enzyme Validator in addition to ALT-, AST- CK-, now includes value assignments for ALP, CHE, GGT, and LD assays and the predicate Enzyme Validator only has value assignments for the ALT-, AST- and CK- assays.

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 that relate results obtained from the noncalibrated SYNCHRON Systems Enzyme Reagents and the calibrated SYNCHRON Systems Enzyme Reagents with the associated SYNCHRON Enzyme Validator.

Method Comparison Study Results
SYNCHRON Systems ALP, CHE, GGT, LD Reagents

Reagent	Slope	Intercept	r	n	Predicate Method
SYNCHRON LX System Calibrated (DGKCh) ALP Reagent	1.426	3.34	0.999	67	SYNCHRON LX System Uncalibrated ALP Reagent
SYNCHRON LX System Calibrated (IFCC) ALP Reagent	1.019	-1.95	0.999	79	SYNCHRON LX System Uncalibrated ALP Reagent
SYNCHRON LX System Calibrated CHE Reagent	0.760	2.56	0.999	72	SYNCHRON LX System Uncalibrated CHE Reagent
SYNCHRON LX System Calibrated GGT Reagent	1.141	-2.18	0.999	79	SYNCHRON LX System Uncalibrated GGT Reagent
SYNCHRON LX System Calibrated LD Reagent	1.242	-0.20	0.996	70	SYNCHRON LX System Uncalibrated LD Reagent

Estimated Imprecision
SYNCHRON LX Systems ALP Reagent

Sample	Mean (IU/L)	S.D. (IU/L)	%C.V.	N
Within-Run Imprecision				
Level 1	39.6	1.77	4.49	80
Level 2	147.9	2.68	1.81	80
Level 3	258.1	1.92	0.75	80
Total Imprecision				
Level 1	39.6	2.24	5.66	80
Level 2	147.9	3.10	2.10	80
Level 3	258.1	2.85	1.10	80

SYNCHRON LX Systems CHE Reagent

Sample	Mean (U/L)	S.D. (U/L)	%C.V.	N
Within-Run Imprecision				
Level 1	2473	35.1	1.3	80
Level 2	3330	31.9	1.0	80
Level 3	8805	85.5	1.0	80
Total Imprecision				
Level 1	2473	46.9	1.9	80
Level 2	3330	49.2	1.5	80
Level 3	8805	157.9	1.8	80

SYNCHRON LX Systems GGT Reagent

Sample	Mean (IU/L)	S.D. (IU/L)	%C.V.	N
Within-Run Imprecision				
Level 1	13.0	1.72	13.23	80
Level 2	194.0	1.84	0.95	80
Level 3	371.7	1.56	0.42	80
Total Imprecision				
Level 1	13.0	2.08	16.01	80
Level 2	194.0	4.25	2.19	80
Level 3	371.7	7.90	2.13	80

SYNCHRON LX Systems LD Reagent

Sample	Mean (IU/L)	S.D. (IU/L)	%C.V.	N
Within-Run Imprecision				
Level 1	62.5	2.2	3.5	80
Level 2	419.0	3.5	0.8	80
Total Imprecision				
Level 1	62.5	2.8	4.5	80
Level 2	419.0	5.3	1.3	80

Stability Study Results

Reagent	Product Claim
SYNCHRON Enzyme Validator	18 month shelf-life

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 23 1997

Lucinda Stockert
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P.O. Box 8000
Brea, California 92822-8000

Re: K971333
SYNCHRON® Systems Enzyme Reagents and Enzyme Validator
Regulatory Class: I & II
Product Code: CJE, DIH, JPZ, CFJ, JIX
Dated: March 28, 1996
Received: April 1, 1996

Dear Ms. Stockert:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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: **SYNCHRON® Systems Alkaline Phosphatase (ALP) Reagent**

Indications for Use:

The SYNCHRON Systems Alkaline Phosphatase (ALP) Reagent, in conjunction with SYNCHRON Enzyme Validator Set, is intended for the quantitative determination of alkaline phosphatase activity in human serum or plasma on SYNCHRON Systems. Use of this product, in conjunction with the SYNCHRON Enzyme Validator Set, will result in assay values which are compatible with those from methods recommended by the International Federation of Clinical Chemistry (IFCC) or the German Society for Clinical Chemistry (Deutsche Gesellschaft fur Klinische Chemie, DGKCh).

21 CFR 862.1050 Alkaline Phosphatase or isoenzymes test system.

(a) *Identification.* An alkaline phosphatase system is a device intended to measure alkaline phosphatase or its isoenzymes (a group of enzymes with similar biological activity) in serum or plasma. Measurements of alkaline phosphatase or its isoenzymes are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

(b) *Classification.* Class II.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K971333

Prescription Use ✓ OR Over-the-Counter Use ___
(per 21 CFR 801.109)

510(k) Number (if known):

Device Name: SYNCHRON® Systems Cholinesterase (CHE) Reagent

Indications for Use:

The SYNCHRON Systems Cholinesterase (CHE) Reagent, in conjunction with SYNCHRON Enzyme Validator Set, is intended for the quantitative determination of pseudo-cholinesterase activity in human serum or plasma on SYNCHRON Systems. Use of this product, in conjunction with the SYNCHRON Enzyme Validator Set, will result in assay values which are compatible with those from methods recommended by the German Society for Clinical Chemistry (Deutsche Gesellschaft fur Klinische Chemie, DGKCh).

21 CFR 862.3240 Cholinesterase test system.

(a) *Identification.* A cholinesterase test system is a device intended to measure cholinesterase (an enzyme that catalyzes the hydrolysis of acetyl-choline to choline) in human specimens. There are two principal types of cholinesterase in human tissues. True cholinesterase is present at nerve endings and in erythrocytes (red blood cells) but is not present in plasma. Pseudo cholinesterase is present in plasma and liver but is not present in erythrocytes. Measurements obtained by this device are used in the diagnosis and treatment of cholinesterase inhibition disorders (e.g., insecticide poisoning and succinylcholine poisoning).

(b) *Classification.* Class I

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109)

510(k) Number (if known):

Device Name: SYNCHRON Systems γ-Glutamyl Transferase Reagent

Indications for Use:

The SYNCHRON Systems γ-Glutamyl Transferase (GGT) Reagent, in conjunction with SYNCHRON Enzyme Validator Set, is intended for the quantitative determination of γ-glutamyl transferase activity in human serum or plasma on SYNCHRON Systems. Use of this product, in conjunction with the SYNCHRON Enzyme Validator Set, will result in assay values which are compatible with those from methods recommended by the International Federation of Clinical Chemistry (IFCC) and the German Society for Clinical Chemistry (Deutsche Gesellschaft fur Klinische Chemie, DGKCh).

21 CFR 862.1360 Gamma-glutamyl transpeptidase and isoenzymes test system.

(a) *Identification.* A gamma-glutamyl transpeptidase and isoenzymes test system is a device intended to measure the activity of the enzyme gamma-glutamyl transpeptidase (GGTP) in plasma and serum. Gamma-glutamyl transpeptidase and isoenzymes measurements are used in the diagnosis and treatment of liver diseases such as alcoholic cirrhosis and primary and secondary liver tumors.

(b) *Classification.* Class I.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109)

510(k) Number (if known):

Device Name: **SYNCHRON® Systems Alkaline Phosphatase (ALP) Reagent**

Indications for Use:

The SYNCHRON Systems Alkaline Phosphatase (ALP) Reagent, in conjunction with SYNCHRON Enzyme Validator Set, is intended for the quantitative determination of alkaline phosphatase activity in human serum or plasma on SYNCHRON Systems. Use of this product, in conjunction with the SYNCHRON Enzyme Validator Set, will result in assay values which are compatible with those from methods recommended by the International Federation of Clinical Chemistry (IFCC) or the German Society for Clinical Chemistry (Deutsche Gesellschaft fur Klinische Chemie, DGKCh).

21 CFR 862.1050 Alkaline Phosphatase or isoenzymes test system.

(a) *Identification.* An alkaline phosphatase system is a device intended to measure alkaline phosphatase or its isoenzymes (a group of enzymes with similar biological activity) in serum or plasma. Measurements of alkaline phosphatase or its isoenzymes are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

(b) *Classification.* Class II.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K971333

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109)

510(k) Number (if known):

Device Name: **SYNCHRON® Systems Cholinesterase (CHE) Reagent**

Indications for Use:

The SYNCHRON Systems Cholinesterase (CHE) Reagent, in conjunction with SYNCHRON Enzyme Validator Set, is intended for the quantitative determination of pseudo-cholinesterase activity in human serum or plasma on SYNCHRON Systems. Use of this product, in conjunction with the SYNCHRON Enzyme Validator Set, will result in assay values which are compatible with those from methods recommended by the German Society for Clinical Chemistry (Deutsche Gesellschaft fur Klinische Chemie, DGKCh).

21 CFR 862.3240 Cholinesterase test system.

(a) *Identification.* A cholinesterase test system is a device intended to measure cholinesterase (an enzyme that catalyzes the hydrolysis of acetyl-choline to choline) in human specimens. There are two principal types of cholinesterase in human tissues. True cholinesterase is present at nerve endings and in erythrocytes (red blood cells) but is not present in plasma. Pseudo cholinesterase is present in plasma and liver but is not present in erythrocytes. Measurements obtained by this device are used in the diagnosis and treatment of cholinesterase inhibition disorders (e.g., insecticide poisoning and succinylcholine poisoning).

(b) *Classification.* Class I

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109)

127