K041643

AUG 18 2004

510(k) Summary
SYNCHRON® Systems Phosphorus (PHS) Reagent

1.0 **Submitted By:**

Mary Beth Tang
Staff Regulatory Affairs Specialist
Beckman Coulter, Inc.
200 S. Kraemer Blvd., W-104
Brea, California 92822-8000
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2.0 **Date Submitted:**

June 15, 2004

3.0 **Device Name(s):**

3.1 **Proprietary Names**
SYNCHRON® Systems Phosphorus (PHS) Reagent

3.2 **Classification Name**
Phosphorus (inorganic) test system (21 CFR § 862.1580)

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
SYNCHRON® Systems PHS Reagent	SYNCHRON® Systems PO4 Reagent	Beckman Coulter, Inc.*	K883181

*Beckman Coulter, Inc., Brea, CA

5.0 **Description:**

The SYNCHRON Systems PHS reagent is designed for optimal performance on the SYNCHRON CX (CX4CE/4Δ/4PRO, CX5CE/5Δ/5PRO, CX7/7RTS/7Δ/7PRO, CX9ALX/9PRO) and LX (LX20/PRO/LXi 725) Systems. The reagent kit contains two 300-test cartridges that are packaged separately from the associated calibrator.

6.0 **Intended Use:**

PHS reagent, in conjunction with SYNCHRON Systems and SYNCHRON Multi Calibrator, is intended for use in the quantitative determination of inorganic phosphorus concentration in human serum, plasma, or urine.

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	
PHS Reagent	Intended Use	Same as Beckman Coulter SYNCHRON CX Systems PO4 Reagent
	Methodology	
	Reactive Ingredients	
	Sample Types	
	Detection Wavelength	
	Reaction Volumes (reagent, sample)	
	Shelf Life	
	Differences	
	Reaction Type (endpoint)	PHS: Sample-blanked PO4: Reagent-blanked
	TCA precipitation method (for serum proteins)	PHS: Compatible PO4: Incompatible
	Instrument Platforms:	PHS: CX CE/Δ/PRO Systems, LX20/PRO/LXi Systems PO4: CX Systems only

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, linearity, and imprecision experiments.

SYNCHRON CX Systems PHS Method Comparison Study Results

Candidate Method	**Sample Type**	**Slope**	**Intercept**	**R**	**n**	**Predicate Method**
SYNCHRON Systems PHS Reagent	Serum	0.997	-0.04	0.998	114	Beckman Coulter SYNCHRON PO4 Assay on CX Systems
	Urine	0.976	0.25	0.996	81	

SYNCHRON LX20 System PHS Estimated Imprecision

Sample	**Mean (mg/dL)**	**S.D. (mg/dL)**	**%C.V.**	**N**
Within-Run Imprecision				
Serum 1	2.0	0.05	2.4	80
Serum 2	6.6	0.09	1.4	80
Urine 1	41.1	0.43	1.0	80
Urine 2	78.3	0.91	1.2	80
Total Imprecision				
Serum 1	2.0	0.05	2.7	80
Serum 2	6.6	0.10	1.5	80
Urine 1	41.1	0.61	1.5	80
Urine 2	78.3	1.26	1.6	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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 1 8 2004

Ms. Mary Beth Tang
Staff Regulatory Affairs Specialist
Beckman Coulter, Inc
200 South Kraemer Blvd.
P.O. Box 8000
Brea, CA 92821

Re: k041643
Trade/Device Name: SYNCHRON® Systems Phosphorus (PHS) Reagent
Regulation Number: 21 CFR 862.1580
Regulation Name: Phosphorus (inorganic) test system
Regulatory Class: Class I
Product Code: CEO
Dated: June 15, 2004
Received: June 17, 2004

Dear Ms. Tang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

K041643

Device Name:

SYNCHRON® Systems Phosphorus (PHS) Reagent

Indications for Use:

PHS reagent, in conjunction with SYNCHRON® Systems and SYNCHRON Multi Calibrator, is intended for use in the quantitative determination of inorganic phosphorus in human serum, plasma, or urine.

Measurements of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.

Prescription Use ___X_____ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041643