

K970919
MAY 21, 1997

Summary of Safety & Effectiveness
SYNCHRON® Systems Uric Acid (URIC) Reagent

1.0 **Submitted By:**

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2.0 **Date Submitted:**

3 March 1997

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON® Systems Uric Acid (URIC) Reagent

3.2 **Classification Name**

Uric Acid test system. (21 CFR § 862.1775)

4.0 **Predicate Device(s):**

Product	Predicate	Predicate Company	Docket Number
Beckman SYNCHRON Systems Uric Acid (URIC) Reagent as used on the SYNCHRON CX Systems	Beckman Dri-STAT® Uric Acid Trinder Reagent	Beckman Instruments, Inc	K881498
SYNCHRON LX Clinical System	SYNCHRON CX Clinical Systems	Beckman Instruments, Inc.	**K965240

****K965240 for the LX SYNCHRON System is currently under review.**

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5.0 **Description:**

The SYNCHRON Systems Uric Acid (URIC) reagent is designed for use with clinical chemistry analyzers from Beckman Instruments, such as the SYNCHRON CX® and LX™ Clinical Systems. When used in conjunction with SYNCHRON MULTI™ Calibrator, it is intended for use in the quantitative determination of uric acid concentration in serum, plasma, and urine samples. Measurements obtained by this device are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

6.0 **Intended Use:**

The SYNCHRON Systems Uric Acid (URIC) reagent, in conjunction with SYNCHRON MULTI™ Calibrator, is intended for use in the quantitative determination of uric acid concentration in serum, plasma, and urine samples. This assay is designed for use with clinical chemistry analyzers from Beckman Instruments, such as the SYNCHRON CX® and LX™ Clinical Systems.

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

Reagent	Aspect/Characteristic	Comments
SYNCHRON Systems (URIC) Reagent	intended use	same: quantitative determination of uric acid in human serum, plasma, and urine
	chemical reaction	same: a timed endpoint methodology
	reagent components and packaging	same: same reagent formulation and packaging materials
	measurement method	same: runs the reaction at 37°C and reads an endpoint at 520 nm
	measuring range default range: serum/plasma	same: (0.5 - 12.0 mg/dL)
	urine range (with on-line or off-line dilution)	(5 - 120 mg/dL)
	calibration	same: single point update

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Differences

Reagent	Aspect/Characteristic	Comments
SYNCHRON Systems (URIC) Reagents	Measuring range expansion	The LX System may utilize ORDAC serum and plasma samples to expand the measuring range to 9.0 mg/dL to 21.0 mg/dL.
	Urine application	the LX System performs the 1:10 sample dilution onboard, where the CX System must have the dilution prepared off-line

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 that relate results obtained from the SYNCHRON Systems Uric Acid Reagent run on the SYNCHRON CX Systems to the SYNCHRON Systems Uric Acid Reagent run on the SYNCHRON Systems LX.

Method Comparison Study Results

Reagent (Analyte)	Slope	Intercept (mg/dL)	r	n	Predicate Method
Serum/Plasma SYNCHRON Uric Acid Reagent (URIC) on the SYNCHRON LX System	0.977	-0.020	0.9985	79	Beckman SYNCHRON Uric Acid Reagent (URIC) on the SYNCHRON CX System
Urine SYNCHRON Uric Acid Reagent (URIC) on the SYNCHRON LX System	0.995	0.116	0.9990	78	Beckman SYNCHRON Uric Acid Reagent (URIC) on the SYNCHRON CX System

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Linearity Study Results

Analyte	Sample Type	Option	Measuring Range	Assessment
SYNCHRON Systems URIC Reagent	serum	default	0.5 - 12.0 mg/dL	linear
		ORDAC	5.0 - 120 mg/dL	linear
	urine	default	5.0 - 120 mg/dL	linear

Estimated Imprecision

SAMPLE	Mean (mg/dL)	SD (mg/dL)	%C.V.	N
Within-Run Imprecision				
Level 1	2.42	0.03	1.1%	80
Level 2	10.48	0.05	0.5%	80
Total Imprecision				
Level 1	2.42	0.05	1.9%	80
Level 2	10.48	0.08	0.8%	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.

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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 21 1997

Sheri Hall

Manager, Premarket Regulatory
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Re: K970919
SYNCHRON® Systems Uric Acid (URIC) Reagent
Regulatory Class: I
Product Code: KNK
Dated: March 5, 1997
Received: March 12, 1997

Dear Ms. Hall:

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

K970919

510(k) Number (if known):

Device Name: **SYNCHRON® Systems
Uric Acid (URIC) Reagent**

Indications for Use:

The SYNCHRON Systems Uric Acid (URIC) Reagent, in conjunction with SYNCHRON MULTI™ Calibrator, is intended for use in the quantitative determination of uric acid in serum, plasma, and urine samples. This assay is designed for use with clinical chemistry analyzers from Beckman Instruments, such as the SYNCHRON CX® and LX™ Clinical Systems.

21 CFR § 862.1775 Uric acid Test System

(a) Identification. A uric acid test system is a device intended to measure uric acid in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

(b) Classification. Class I.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy Moore for Al Montgomery DVM

(Division Sign-Off)

Director of Clinical Laboratory Devices

510(k) Number

K970919

Prescription Use (per 21 CFR 801.109)

OR

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

PC