DEC 1 2 2001

BECKMAN COULTER

510(k) Summary
SYNCHRON® Systems Vancomycin Reagent and Calibrator

K013076

1.0 **Submitted By:**

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2.0 **Date Submitted:**

September 12, 2001

3.0 **Device Name(s):**

3.1 **Proprietary Names:**
SYNCHRON® Systems Vancomycin Reagent and Calibrator

3.2 **Classification Name:**
Vancomycin test system (21 CFR § 862.3950)
Clinical toxicology calibrator (21 CFR § 862.3200)

4.0 **Predicate Device(s):**

Beckman Coulter	Predicate	Manufacturer	Docket Number
SYNCHRON® Systems Vancomycin (VANC) Reagent and Calibrator	AxSYM® Vancomycin II Assay	Abbott Laboratories, Inc.*	K955851

*Abbott Laboratories, Inc., Abbott Park, IL

5.0 **Description:**

The SYNCHRON System Vancomycin (VANC) Reagent and Calibrator are designed for optimal performance on the SYNCHRON CX (CX4/4CE/4Δ/4PRO, CX5/5CE/5Δ/5PRO, CX7/7RTS/7Δ/7PRO, CX9ALX/9PRO) and LX (LX20/PRO) Systems. The assay is intended for use in the quantitative determination of vancomycin concentration in human serum or plasma. The reagent kit contains two 100-test cartridges and is packaged separately from the six-level calibrator set.

6.0 **Intended Use:**

The SYNCHRON Systems Vancomycin (VANC) Reagent, in conjunction with the SYNCHRON Systems Vancomycin Calibrator set, is intended for the quantitative determination of vancomycin concentration in human serum or plasma on SYNCHRON Systems.

The SYNCHRON Systems Vancomycin Calibrator, used in conjunction with SYNCHRON Vancomycin Reagent, is intended for use on the SYNCHRON Systems for the calibration of Vancomycin.

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

Assay	Aspect/Characteristic	Comments
SIMILARITIES		
SYNCHRON® Systems VANC Reagent and Calibrator	Intended use	Same as predicate
	Sample Type	
	Antibody source (mouse monoclonal)	
	Liquid-stable reagents and calibrators	
	Storage conditions (+2°C to +8°C)	
DIFFERENCES		
	Methodology	**SYNCHRON:** Turbidimetric Inhibition Immunoassay **AxSYM:** Fluorescence Polarization Immunoassay (FPIA)
	Formulation	Specific to methodology
	Reportable Range	**SYNCHRON:** CX: 3.5 – 50 µg/mL LX: 3.5 – 40 µg/mL LX: ORDAC* 30 – 60 µg/mL **AxSYM:** 2 – 100 µg/mL
	Sensitivity	**SYNCHRON:** 3.5 µg/mL **AxSYM:** 2 µg/mL
	Sample Size	**SYNCHRON:** 3 µL, 2 µL (LX ORDAC) **AxSYM:** 150µL, 94 µL (STAT)

*ORDAC = Over Range Detection and Correction

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 and imprecision experiments that relate results obtained from the SYNCHRON Vancomycin Assay to the Abbott AxSYM Vancomycin assay.

Method Comparison Study Results*

Analyte	N	Slope	Intercept	r	Predicate Method
SYNCHRON Vancomycin Assay	100	1.096	-2.63	0.983	Abbott AxSYM Vancomycin Assay

*Serum patient specimens were analyzed in the range of 3.6 to 51.6 µg/mL vancomyucin. Data shown was collected using SYNCHRON LX Systems. Equivalency between SYNCHRON LX and SYNCHRON CX Systems has been established by correlation analysis.

Estimated SYNCHRON LX Vancomycin Assay Imprecision

Sample	Mean (µg/mL)	S.D. (%)	%C.V.	N
Within-Run Imprecision				
Level 1	8.2	0.44	5.3	80
Level 2	21.6	0.37	1.7	80
Level 3	36.2	0.69	1.9	80
Total Imprecision				
Level 1	8.2	0.58	7.0	80
Level 2	21.6	0.48	2.2	80
Level 3	36.2	0.89	2.5	80

The Summary of Safety and Effectiveness information for the SYNCHRON Systems Vancomycin Reagent and Calibrator are found in TAB 1 of this notice and are being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 2 2001

Ms. Mary Beth Tang
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Re: k013076
Trade/Device Name: SYNCHRON® Systems Vancomycin Reagent and Calibrator
Regulation Number: 21 CFR 862.3950
Regulation Name: Vancomycin test system
Regulatory Class: Class II
Product Code: LEH
Dated: November 28, 2001
Received: November 29, 2001

Dear Ms. Tangl:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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): **K013076**

Device Name: **SYNCHRON® Systems Vancomycin Reagent and Calibrator**

Indications for Use:

The SYNCHRON® Systems Vancomycin (VANC) Reagent, in conjunction with the SYNCHRON® Systems Vancomycin Calibrator set, is intended for the quantitative determination of vancomycin concentration in human serum and plasma on SYNCHRON Systems by turbidimetric immunoassay.

The SYNCHRON® Systems Vancomycin Calibrator, used in conjunction with SYNCHRON® Vancomycin Reagent, is intended for use on the SYNCHRON Systems for the calibration of Vancomycin.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013076

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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