JAN 29 1999

K984402

BECKMAN COULTER

Summary of Safety & Effectiveness
SYNCHRON® Systems Ammonia (AMM) Reagent

1.0 **Submitted By:**

Lucinda Stockert
Staff Regulatory Specialist, Product Submissions
Beckman Coulter, Inc.
200 S. Kraemer Blvd., W-104
Brea, California 92822-8000
Telephone: (714) 961-3777
FAX: (714) 961-4123

2.0 **Date Submitted:**

December 7, 1998

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON® Systems Ammonia (AMM) Reagent

3.2 **Classification Name**

Ammonia (21CFR §862.1065)

4.0 **Predicate Device(s):**

SYNCHRON Systems Reagent	Predicate	Manufacturer	Docket Number
SYNCHRON® Systems Ammonia (AMM)	Ammonia reagent on the Dade aca®* clinical analyzer	Dade Behring, Inc	K770363

*Trademark of Dade Behring Inc. – formerly DuPont

5.0 **Description:**

The SYNCHRON System Ammonia Reagent is designed for optimal performance on the SYNCHRON CX and LX Systems. It is intended for use in the quantitative determination of ammonia in plasma.

6.0 Intended Use:

The SYNCHRON® Systems Ammonia (AMM) Reagent, in conjunction with SYNCHRON® Systems Ammonia Calibrators, is intended for the quantitative determination of ammonia concentration in plasma on SYNCHRON® Systems.

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	
SYNCHRON® Systems Ammonia	SYNCHRON assay uses GLDH enzymatic method for measuring ammonia at 37°C.	Same as Dada aca Reagent
	GLDH source is beef liver	
	The reagent is ready to load onto the instrument (requires no user preparation).	
	Reagent measures ammonia in human plasma.	
	DIFFERENCES	
	Reagent components	All components of the SYNCHRON Ammonia reagent are liquid Some components of the Dade aca Ammonia reagent are in tablets and others are liquid.
	Sample Volume	SYNCHRON Ammonia assay requires 25 µL of sample. aca assay requires 500 µL of sample.
	Type of measurement	SYNCHRON Ammonia is a timed endpoint assay. Dade aca is a rate assay.

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.

Method Comparison Study Results
SYNCHRON® Systems Digoxin (DIGN) Reagent

SYNCHRON DIGN Reagent	Sample Type	Slope	Intercept (µmol/L)	r	n	Predicate Method
SYNCHRON CX System	Plasma	1.018	-5.3	0.9991	82	Dade aca
SYNCHRON LX System	Plasma	1.003	-2.2	0.9986	82	Dade aca

Estimated Within-Run Imprecision

SYNCHRON System	Sample	Mean (µmol/L)	S.D. (µmol/L)	%C.V.	N
CX	Level 1	48	2.6	4.2	15
	Level 2	128	3.0	2.3	15
	Level 3	644	5.3	0.8	15
LX	Level 1	48	2.3	4.9	15
	Level 2	128	2.8	2.2	15
	Level 3	644	4.9	0.8	15

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

JAN 29 1999

Lucinda Stockert
Staff Regulatory Specialist, Product Submissions
BECKMAN COULTER, INC.
200 S. Kraemer Blvd., W-104
Brea, California 92822-8000

Re: K984402
Trade Name: SYNCHRON® Systems Ammonia (AMM) Reagent
Regulatory Class: I
Product Code: JIF
Dated: December 7, 1998
Received: December 9, 1998

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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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/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): K984402

Device Name: **SYNCHRON® Systems**
Ammonia (AMM) Reagent

Indications for Use:

The SYNCHRON® Systems Ammonia (AMM) Reagent, in conjunction with SYNCHRON® Systems Ammonia Calibrators, is intended for the quantitative determination of ammonia concentration in plasma on SYNCHRON® Systems.

Clinical Significance:

An ammonia test system is a device intended to measure ammonia levels in blood, serum, and plasma. Ammonia measurements are used in the diagnosis and treatment of severe liver disorders, such as cirrhosis, hepatitis, and Reye's syndrome.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984402

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-the-Counter Use ____
(per 21 CFR 801.109) Optional Format 1-2-96