

K971958

Beckman Instruments, Inc., Section 510(k) Notification  
SYNCHRON LX™ Systems Transferrin (TRFN) Reagent  
Summary of Safety & Effectiveness

AUG 20 1997

Summary of Safety & Effectiveness  
SYNCHRON LX™ Systems Transferrin (TRFN) Reagent

1.0 **Submitted By:**

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2.0 **Date Submitted:**

21 May 1997

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON LX™ Systems Transferrin (TRFN) Reagent

3.2 **Classification Names**

Transferrin immunological test system (21 CFR 866.5880)

4.0 **Predicate Device(s):**

SYNCHRON LX Reagents	Predicate	Predicate Company	Docket Number
Transferrin (TRFN) Reagent	Beckman Transferrin (TRFN) Reagent	Beckman Instruments, Inc.	K780913

5.0 **Description:**

The SYNCHRON LX Systems Transferrin (TRFN) Reagent in conjunction with SYNCHRON LX Calibrator 1, is intended for use on Beckman's SYNCHRON LX™20 Clinical Systems.

6.0 **Intended Use:**

The SYNCHRON LX Systems Transferrin (TRFN) Reagent, when used in conjunction with SYNCHRON LX Calibrator 1, is intended for the quantitative determination of human transferrin in serum or plasma. This assay is designed for use with clinical chemistry analyzers from Beckman Instruments, such as the SYNCHRON LX™20 Clinical System.

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

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

Reagent	Aspect/Characteristic	Comments
<b>SIMILARITIES</b>		
SYNCHRON LX Systems (TRFN) Reagent	Intended use	Same as the ARRAY System TRFN reagent quantitative determination of human transferrin
	Chemical reaction	Same principle as the ARRAY System TRFN reagent; formation of antigen-antibody complexes
	Antibody	Same source, antibody, processing, and buffer as the ARRAY System TRFN reagent
	Calibration	Same as the ARRAY System TRFN reagent; single point update of manufacturer determined calibration curve

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Reagent	Aspect /Characteristic	Comments
<b>DIFFERENCES</b>		
SYNCHRON LX Systems (TRFN) Reagent	Methodology	The SYNCHRON LX reads turbidimetrically and the ARRAY System reads nephelometrically
	Measurement method	The SYNCHRON LX runs the reaction at 37°C and reads an endpoint at 340 nm, where the ARRAY System runs at 26.5°C and reads the rate of increase in light scatter at 670 nm
	Range expansion	The SYNCHRON LX TRFN reagent measures transferrin concentrations at the initial range of 75 - 800 mg/dL; while the ARRAY TRFN reagent measures transferrin concentrations at the initial range of 75-800 mg/dL and expanded range of 12.5 - 4,500 mg/dL
	Type of specimen	The SYNCHRON LX TRFN reagent measures transferrin concentrations in serum or plasma samples; while the ARRAY Systems TRFN reagent measures transferrin concentrations in serum (plasma samples are not recommended) or urine samples.
	Antigen excess checking	The SYNCHRON LX TRFN reagent was designed so that high antigen concentrations will not report in range; the ARRAY System adds extra antibody to observe for additional activity
	Packaging	The SYNCHRON LX TRFN reagent is packaged in polystyrene cartridges; the ARRAY System TRFN reagent is packaged in glass bottles

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 Beckman's Immunochemistry System TRFN Transferrin (on ARRAY) Reagent to the SYNCHRON LX Transferrin (TRFN) Reagent.

Method Comparison Study Results  
 SYNCHRON LX Transferrin (TRFN) Reagent vs.  
 Beckman TRFN Transferrin Reagent (on ARRAY)

Reagent (Analyte)	Slope	Intercept (mg/dL)	r	n	Predicate Method
The SYNCHRON LX Transferrin (TRFN) Reagent	1.041	-20.7	0.9844	80	Beckman's TRFN Transferrin Reagent on the ARRAY® Systems

Stability Study Results

Reagent	Product Claim
SYNCHRON LX Transferrin (TRFN) Reagent	24 month shelf-life 14 day calibration stability 60 days on-board stability

Estimated Within-Run Imprecision

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
SYNCHRON LX Transferrin (TRFN) Reagent				
Level 1	135.7	2.00	1.47	80
Level 2	218.6	2.95	1.35	80
Level 3	303.5	4.08	1.34	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

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Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

AUG 20 1997

Re: K971958/S1  
Trade Name: SYNCHRON LX™ Systems Transferrin (TRFN) Reagent  
Regulatory Class: II  
Product Code: DDG  
Dated: July 31, 1997  
Received: August 5, 1997

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 current Good Manufacturing Practice requirement, 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.

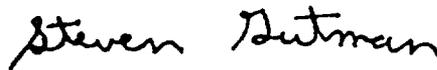
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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 at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>"

Sincerely yours,



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

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510(k) Number (if known): K971958

Device Name: **SYNCHRON LX™ Systems Transferrin (TRFN) Reagent**

Indications for Use:

The SYNCHRON LX Systems Transferrin (TRFN) Reagent, when used in conjunction with SYNCHRON LX Calibrator 1, is intended for the quantitative determination of human transferrin in serum or plasma. This assay is designed for use with clinical chemistry analyzers from Beckman instruments, such as the SYNCHRON LX20 Clinical System.

The measurement of transferrin in serum or other body fluids aids in the diagnosis of malnutrition, acute inflammation, infection, assessment of renal function and red blood cell disorders, such as iron deficiency anemia.

21 CFR 866.5880 Transferrin immunological test system

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
DIVISION **Sign-Off**  
DIVISION of **Clinical Laboratory Devic**  
510(k) Number \_\_\_\_\_

Prescription Use  \_\_\_\_\_  
(per 21 CFR 801.109)

OR

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