

Beckman Instruments, Section 510(k) Notification
SYNCHRON Systems Lipase Reagent
Summary of Safety and Effectiveness

K970905

1. Submitted by:

Sheri Hall
Product Submissions Manager
Beckman Instruments, Inc.
200 S. Kraemer Blvd., W-337
Brea, California 92822-8000
Telephone: (714) 993-8916, FAX (714) 961-4457

JUN - 4 1997

2. Date Submitted:

3 March 1997

3. Device Name(s):

SYNCHRON® Systems Lipase (LIPA) Reagent
Lipase test system (21 CFR 862.1465)

4. Predicate Device(s):

	Predicate	Predicate Company	Docket Number
SYNCHRON CX Systems Lipase (LIPA) Reagent	Genzyme Lipase Reagent	Toyo Jozo Co., Ltd (Japan)	K952180
SYNCHRON LX Clinical System	SYNCHRON CX Clinical System	Beckman Instruments, Inc.	K965240

5. Description:

This assay is designed for use with clinical chemistry analyzers from Beckman Instruments, such as the SYNCHRON CX® AND LX™ Clinical Systems. The SYNCHRON Systems Lipase (LIPA) Reagent, when used in conjunction with SYNCHRON Systems Lipase Calibrator, is intended for use in the quantitative determination of pancreatic lipase activity in serum or plasma samples. Lipase measurements are used in diagnosis and treatment of diseases of the pancreas such as acute pancreatitis and obstruction of the pancreatic duct.

6. Intended Use:

The SYNCHRON Systems Lipase (LIPA) Reagent, in conjunction with SYNCHRON Systems Lipase Calibrator, is intended for use in the quantitative determination of pancreatic lipase activity in serum or plasma samples. This assay is designed for use with clinical chemistry analyzers from Beckman Instruments, such as the SYNCHRON CX and LX Clinical Systems.

7. Comparison to the Predicate:

The SYNCHRON Systems Lipase (LIPA) Reagent is similar to the predicate in the intended use, chemical reaction, reagent components and packaging, measurement method, default measuring range, and calibration method. They differ in the SYNCHRON Systems Lipase Reagent uses the system ORDAC (over range detection and correction) feature to expand the measuring range to 1200 U/L.

Beckman Instruments, Section 510(k) Notification
 SYNCHRON Systems Lipase Reagent
 Summary of Safety and Effectiveness

8. Summary of Performance Data:

The data in the Premarket Notification supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. A summary of the data follows:

Method Comparison

Reagent	Slope	Intercept (U/L)	r	n	Predicate Method
SYNCHRON Systems Lipase Reagent on the LX System	1.068	-0.42	0.997	91	SYNCHRON Systems Lipase Reagent on the CX System

Linearity

Sample Type	Measuring Option	Measuring Range	Assessment
serum	default	5 - 600 U/L	linear
	ORDAC	480 - 1200 U/L	linear

Imprecision

Sample	Mean (U/L)	S.D. (U/L)	%C.V.	n
Within-Run Imprecision				
Level 1	109.53	1.51	1.38	80
Level 2	269.80	4.15	1.54	80
Level 3	16.33	1.17	7.18	80
Total Imprecision				
Level 1	109.53	2.50	2.28	80
Level 2	269.80	6.03	2.24	80
Level 3	16.33	1.59	9.77	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.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 4 1997

Sheri Hall
• Manager, Premarket Regulatory
Beckman Instruments, Inc.
200 S. Kraemer Boulevard, M/S W-337
P.O. Box 8000
Brea, California 92822-8000

Re: K970905
SYNCHRON® Systems Lipase (LIPA) Reagent
Regulatory Class: II
Product Code: CHI, JIT
Dated: April 28, 1997
Received: May 2, 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.

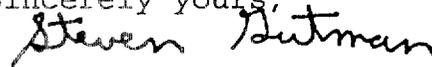
Page 2

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 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):

Device Name: **SYNCHRON® Systems
Lipase (LIPA) Reagent**

Indications for Use:

The SYNCHRON Systems Lipase (LIPA) Reagent, in conjunction with SYNCHRON® Systems Lipase Calibrator, is intended for use in the quantitative determination of pancreatic lipase activity in serum or plasma samples. This assay is designed for use with clinical chemistry analyzers from Beckman Instruments, such as the SYNCHRON CX® and LX™ Clinical Systems.

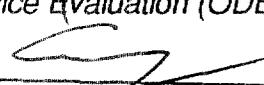
21 CFR § 862.1465 Lipase Test System

(a) Identification. A lipase test system is a device intended to measure the activity of the enzyme lipase in serum. Lipase measurements are used in diagnosis and treatment of diseases of the pancreas such as acute pancreatitis and obstruction of the pancreatic duct.

(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)



(Division Sign Off)
Division of Clinical Laboratory Devices
510(k) Number K 970905

Prescription Use
(per 21 CFR 801.109)

OR

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