JAN 31 2003

Bayer

Assigned 510(k) number: K030169

Business Group
Diagnostics

Bayer Corporation
511 Benedict Avenue
Tarrytown, NY 10591-5097
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Bayer Healthcare
SETpoint Chemistry Calibrator
Summary of Safety and Effectiveness

As required by 21 CFR 807.92, the following 510(k) Summary is provided:

1. Submitter Information

Contact person: Kenneth T. Edds Ph.D.

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Bayer Healthcare
Diagnostics Division
511 Benedict Ave.
Tarrytown, NY 10591

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Date Summary Prepared: January 15, 2003

2. Device Information

Proprietary Name: SETpoint Chemistry Calibrator
Common Name: Calibrator for multiple analytes

Classification Name: Calibrator §862.1150.
Class: Class II
CFR: 862.1150
Product Code: 75 JIX

3. Predicate Device Information

Name: Calibrator for automated systems

Manufacturer: Roche Diagnostics Corp.
9115 Hague Rd.
Indianapolis, IN 46250

510(k) Number: K990460

4. Device Description

The SETpoint Chemistry Calibrator is a bovine serum based solution containing various nonhuman constituents at defined concentrations.

5. Statement of Intended Use

Bayer SETpoint Calibrator is intended for *in vitro* diagnostic use to calibrate the following systems: Technicon RA and opeRA Chemistry Systems, Technicon RA-100, Technicon DAX, ADVIA 1650/ADVIA 2400 Chemistry systems, and ADVIA IMS Chemistry systems.

6. Product Performance

The stability of the SETpoint calibrator values has been validated according to Bayer procedures and is based on the results of three separate lots of calibrator material. The performance of the calibrator is similar to other products in commercial distribution intended for similar use.

7. Product Characteristics

Characteristic	**Bayer SETpoint Calibrator**	**Roche Calibrator for Automated Systems**
Intended Use	Bayer SETpoint Calibrator is intended for *in vitro* diagnostic use to calibrate the following systems: Technicon RA and opeRA Chemistry Systems, Technicon RA-100, Technicon DAX, ADVIA 1650/ADVIA 2400 Chemistry systems, and ADVIA IMS Chemistry systems.	For use as a calibrator of clinical chemistry assays for automated analytical procedures.
Format	Lyophilized bovine serum base to which appropriate nonhuman constituents have been added to achieve specific concentrations.	Lyophilized pooled human serum with constituents added as required to obtain desired component levels.
Stability	• Stable at 2-8°C until last day of the month (expiration date) printed on label. • Stable 48 hours when reconstituted according to directions when refrigerated at 2-8°C and protected from light with the exception of total and direct bilirubin, which are stable for eight hours.	• Stable at 2-8°C until expiration date. • Stable 2 days when reconstituted, stoppered, protected from light and stored at 2-8°C, with exceptions noted in labeling.
Levels	Single Level	Single Level

Constituent Analytes

Bayer SETpoint (New Device)	Roche Calibrator for Automated Systems (C.f.a.s) (Predicate Device)
ALBUMIN	ALBUMIN
BILIRUBIN, DIRECT	BILIRUBIN, DIRECT
BILIRUBIN, TOTAL	BILIRUBIN, TOTAL
CALCIUM	CALCIUM
CHOLESTEROL	CHOLESTEROL
CREATININE	CREATININE
GLUCOSE	GLUCOSE
IRON	IRON
MAGNESIUM	MAGNESIUM
PHOSPHORUS, INORGANIC	PHOSPHORUS, INORGANIC
TOTAL PROTEIN	TOTAL PROTEIN
TRIGLYCERIDES	TRIGLYCERIDES
UREA NITROGEN	UREA NITROGEN
URIC ACID	URIC ACID
SODIUM	SODIUM
POTASSIUM	POTASSIUM
CHLORIDE	CHLORIDE
	LACTATE
	PHOSPHOLIPIDS
	SALICYLATE
	UNSATURATED IRON-BINDING CAPACITY
	ACID PHOSPHATASE
	ALKALINE PHOSPHATASE
	ALANINE AMINOTRANSFERASE
	ALPHA-AMYLASE
	PANCREATIC ALPHA-AMYLASE
	ASPARTATE AMINOTRANSFERASE
	CHOLINESTERASE
	CREATINE KINASE
	GAMMA-GLUTAMYLTRANSERASE
	GLUTAMATE DEHYDROGENASE
	ALPHA-HYDROXYBUTYRATE DEHYDROGENASE
	LACTATE DEHYDROGENASE
	LIPASE
	BICARBONATE
	UIBC
	LDI

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 31 2003

Kenneth T. Edds, Ph.D.
Manager, Regulatory Affairs
Bayer Healthcare, LLC
Diagnostics Division
511 Benedict Avenue
Tarrytown, NY 10591-5097

Re: k030169
Trade/Device Name: SETpoint Chemistry Calibrator
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: January 16, 2003
Received: January 17, 2003

Dear Dr. Edds:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030169

Device Name: SETpoint Chemistry Calibrator

Indications for Use:

Bayer SETpoint Calibrator is intended for *in vitro* diagnostic use to calibrate the following systems: Technicon RA and opeRA Chemistry Systems, Technicon RA-100, Technicon DAX, ADVIA 1650/ADVIA 2400 Chemistry systems, and ADVIA IMS Chemistry systems.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K030169

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use

(Per 21 CFR 801.109) **(Optional Format 1-2-96)**