AUG - 6 2003

Assigned 510(k) number: K031683

Bayer Healthcare

ToxAmmonia 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.
Address: Bayer Healthcare Diagnostics Division 511 Benedict Ave. Tarrytown, NY 10591	
Phone:	(914) 524-2446
FAX:	(914) 524-2500
e-mail:	ken.edds.b.@bayer.com

Date Summary Prepared:	August 6, 2003

2. Device Information

Proprietary Name:	Toxammonia Calibrator
Common Name:	Calibrator for multiple analytes
Classification Name:	Calibrator §862.1150.
Class:	Class II
CFR:	862.1150
Product Code:	75 JIX

Contract Manufacturing Site:
Medical Analysis Systems, Inc. (MAS)
5300 Adolfo Rd.
Camarillo, CA 93012

3. Predicate Device Information

Name: SetPoint Chemistry Calibrator

Contract Manufacturing Site:
Fisher Diagnostics
8365 Valley Pike
Middletown, VA 22645

510(k) Number: K030169

4. Device Description

The Toxammonia Calibrator is a human serum based solution containing various nonhuman constituents at defined concentrations.

5. Statement of Intended Use

Bayer Toxammonia Calibrator is intended for *in vitro* diagnostic use to calibrate Acetaminophen, Ammonia, Ethanol and Salicylate assays on the ADVIA IMS Chemistry systems.

6. Product Performance

The stability of the Toxammonia 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. Comparison to Predicate Device

Characteristic	**Bayer ToxAmmonia Calibrator**	**Bayer SETpoint™ Calibrator for Automated Systems**
Intended Use	Bayer ToxAmmonia Calibrator is intended for *in vitro* diagnostic use to calibrate acetaminophen, ammonia, ethanol and salicylate assays on the ADVIA IMS chemistry systems.	For use as a calibrator of clinical chemistry assays for automated analytical procedures.
Format	Liquid human serum albumin base to which appropriate nonhuman constituents have been added to achieve specific concentrations.	Lyophilized bovine serum base to which appropriate nonhuman constituents have been added to achieve specific concentrations.
Stability	• Stable at 2-8°C until the expiration date printed on label. • Stable 3 days after opening when refrigerated at 2-8°C.	• Stable at 2-8°C until last day of the month (expiration date) printed on the 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.
Levels	Single Level	Single Level

Comparison of Constituent Analytes in predicate device and proposed Bayer ToxAmmonia Calibrator

Bayer ToxAmmonia Calibrator (New Device)	Bayer SETpoint™ Chemistry Calibrator (Predicate Device)
ACETAMINOPHEN	ALBUMIN
AMMONIA	BILIRUBIN, DIRECT
ETHANOL	BILIRUBIN, TOTAL
SALICYLATE	CALCIUM
	CHOLESTEROL
	CREATININE
	GLUCOSE
	IRON
	MAGNESIUM
	PHOSPHORUS, INORGANIC
	TOTAL PROTEIN
	TRIGLYCERIDES
	UREA NITROGEN
	URIC ACID
	SODIUM
	POTASSIUM
	CHLORIDE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG - 6 2003

Kenneth T. Edds, Ph.D.
Manager, Regulatory Affairs
Bayer HealthCare
511 Benedict Avenue
Tarrytown, New York 10591-5097

Re: k031683
Trade/Device Name: ToxAmmonia Calibrator
Regulation Number: 21 CFR § 862.1150
Regulation Name: Multianalyte Calibrator
Regulatory Class: II
Product Code: JIX
Dated: May 23, 2003
Received: June 12, 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: K031683

Device Name: ToxAmmonia Calibrator

Indications for Use:
Bayer ToxAmmonia Calibrator is intended for *in vitro* diagnostic use to calibrate Acetaminophen, Ammonia, Ethanol and Salicylate assays on the ADVIA IMS Chemistry systems.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C Benson for Jean Cooper, DVM

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031683

Prescription Use X OR Over-The-CounterUse_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)