BIO-RAD

Bio-Rad Laboratories

Diagnostics Group
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DEC 21 1999

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: 993107.

Submitter:	Bio-Rad Laboratories Diagnostics Group 4000 Alfred Nobel Drive Hercules, California 94547 Phone: (510) 741-6263 FAX: (510) 741-6471
Contact Person:	Patricia M. Klimley Regulatory Affairs Consultant
Date of Summary Preparation:	September 16, 1999 and November 29, 1999
Device Name:	Bio-Rad Homocysteine by HPLC
Classification Name:	Urinary homocysteine (non-quantitative) test system
Predicate Device:	Axis® Homocysteine Enzyme Immunoassay Axis® Biochemicals, ASA Oslo, Norway K980907
Statement of Intended Use:	The Bio-Rad Homocysteine by HPLC test is intended for the quantitative determination of total Homocysteine in human plasma or serum. For in vitro diagnostic use only.

Description of Device

The Bio-Rad Homocysteine by HPLC test is based on precolumn derivatization and a 5 minute chromatography. The precolumn derivatization includes a release of the plasma/serum bound fraction of Homocysteine by a chemical reduction and subsequent fluorescent labeling with a thiolspecific dye. Reduction and derivatization require only 5 minute incubation. Separation of Homocysteine, Internal Standard and other biological thiols (Glutathione, Cysteine, Cysteinglycine) takes place on a selected Reversed Phase cartridge followed by fluorescence detection (l_{ex} = 385 nm, l_{em} = 515 nm). Quantitative analysis is performed using the Bio Rad Clinical Data Management System (K960392).

Testing To Establish Substantial Equivalence

To establish substantial equivalence to an existing device, and thus establish the safety and effectiveness, the Bio-Rad Homocysteine by HPLC is compared to the AXIS® Homocysteine Enzyme Immunoassay (K980907). A review of the intended use of each system shows them to be the same, in that, both methods are intended for the quantitative measurement of homocysteine.

Technical Characteristics Compared to Predicate

Parameter	Bio-Rad Homocysteine by HPLC	AXIS®Homocysteine Enzyme Immunoassay
Analytes Measured/Reported	Homocysteine	Homocysteine
Basic Principle	Chromatography	Immunoassay
Derivatization	Pre-column	Enzymatic conversion to SAH
Separation Mechanism	Reverse Phase	Monoclonal Antibody
Detection Mechanism	Fluorescence	Spectrophotometric
Measurement Type	Quantitative	Quantitative
Sample Type	Serum or Plasma	Serum or Plasma
Calibrators	Single (15 - 20 µMol/L)	2, 4, 8, 15, 30, & 50 µMol/L
Reportable Range	0.5 - 100 µMol/L	2 - 50 µMol/L
Precision	µMol/L: Within Run Total Low 8.25 3.77% 4.40% Mid 19.53 1.87% 2.60% High 39.96 1.16% 2.74%	µMol/L: Within Run Total Low 6.1 7.3% 9.3% Mid 10.3 6.8% 8.1% High 21.4 5.2% 7.1%
Sensitivity	0.5 µMol/L	0.5 µMol/L
Expected Values (95% Confidence Limit)	5.7 - 15.1 µMol/L	5 - 15 µMol/L

A correlation study to determine accuracy of the Bio-Rad Laboratories Homocysteine by HPLC assay was done against the AXIS® Homocysteine Enzyme Immunoassay method. The coefficient of correlation was 0.9472, the slope was 1.023, and the Y-Intercept was -0.542.

When considering an excellent correlation between the AXIS® Homocysteine Enzyme Immunoassay and the Bio-Rad Laboratories Homocysteine by HPLC method, it can be concluded that the Bio-Rad Laboratories Homocysteine by HPLC assay is substantially equivalent to the AXIS® Homocysteine Enzyme Immunoassay method, which has been 510K cleared. Based on the establishment of substantial equivalence, the safety and effectiveness of the Bio-Rad Laboratories Homocysteine by HPLC assay is confirmed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 21 1999

Ms. Patricia M. Klimley
Regulatory Affairs Consultant
Bio-Rad Laboratories, Inc.
Diagnostics Group
4000 Alfred Nobel Drive
Hercules, California 94547

Re: K993107
Trade Name: Homocysteine by HPLC
Regulatory Class: II
Product Code: LPS, JIT
Dated: November 29
Received: November 30

Dear Ms. Klimley

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

Statement of Indications for Use

510(k) Number: K993107

Device Name: Bio-Rad Homocysteine by HPLC

Indications for Use:

The Bio-Rad Homocysteine by HPLC test is intended for the quantitative determination of total Homocysteine in human plasma or serum.

The device can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia or homocysteinuria.

For in vitro diagnostic use only.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993107

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescriptive Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)