K980812

OCT 1 1998

510(k) Summary
IMx® Homocysteine
Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination

The following information as presented in the Premarket Notification [510(k)] for IMx Homocysteine constitutes data supporting a substantially equivalent determination.

IMx Homocysteine is a Fluorescence Polarization Immunoassay for the quantitative measurement of total L-homocysteine in human serum or plasma on the IMx Analyzer. IMx Homocysteine is calibrated with IMx Homocysteine Calibrators. IMx Homocysteine Controls are assayed for the verification of the accuracy and precision of the Abbott IMx Analyzer.

There are several 510(k) cleared methods for measurement of amino acids. [1,2,3] All these methods are based on HPLC separation and either traditional post-column derivatization (LKB, Beckman) or pre-column derivatization (Waters). Homocysteine can be analyzed using a traditional HPLC method with post-column derivatization. For example, Poele-Pothoff[4] et al. Used a traditional system with 3 hours analysis for this purpose (LKB analyzer). Sera were reduced using dithiothreitol, then proteins were precipitated as would normally be done for this instrument. Candito[5] et al. also published an analysis of homocysteine using a Beckman Amino Acid Analyzer, after reduction with dithiothreitol. Both of these methods are based on earlier work by Andersson[6], which used a modified separation on an amino acid analyzer.

To establish substantial equivalence to an existing device, and thus establish the safety and effectiveness of the IMx Homocysteine Assay, the IMx assay was compared to the University of Bergen Homocysteine HPLC mehtod.[7] This method uses pre-column derivitization and permits rapid analysis. In the work of Poele-Pothoff, a similar pre-column method was compared to an amino acid analyzer method and was shown to give an excellent correlation. In addition, the Bergen HPLC method was shown to be equivalent to the amino acid analysis for detection of homocysteine.[8]

---

1. LKB Instruments Inc. 4150 Alpha Amino Acid Analyzer. 510(k) Number: K820415, 02/11/82.
2. Beckman Instruments Inc. System 6300 Series High Performance Amino Acid Analyzer. 510(k) Number: K92093, 11/16/92.
3. Waters Chromatography Division. Waters Pico Tag Chem Pack. Free Amino Acid Analysis Kit. 510(k) Number: K943978, 05/02/95.
4. Poele-Pothoff et al. Ann Clin Biochem. 1995; 32:218-220.
5. Andersson et al. Scand J Clin Lab Invest. 1989;49:445-449.
6. Candito et al. J of Chromatography. 1997;692:213-216.
7. Fiskerstrand et al. Clin Chem. 1993; 39:263-271.
8. Refsum et al. Clin Chem. 1989;35:1921-7.

Substantial equivalence has been demonstrated between the IMx Homocysteine assay and the Bergen HPLC method for measuring total homocysteine. The intended use of both assays is for the quantitative measurement of total homocysteine. Both the IMx Homocysteine assay and the HPLC total homocysteine assay can be performed with human serum of plasma (lithium heparin or tripotassium EDTA). A correlation analysis between these two assays, using 114 specimens, yielded a correlation coefficient of 0.989, slope of 0.980, and y-intercept of 0.12 µmol/L.

In conclusion, these data demonstrate that the IMx Homocysteine assay is as safe and effective as, and is substantially equivalent to the HPLC total homocysteine assay.

Prepared and submitted by:

10 Sept. 98

Ronald G. Leonardi, Ph. D.
President
R&R Registrations
P.O. Box 262069
San Diego, CA 92196
Phone (619) 586-0751

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 1 1998

Ronald G. Leonardi, Ph.D.
President
R & R Registrations
P.O. Box 262069
San Diego, California 92196-2069

Re: K980812
IMx® Homocysteine
Regulatory Class: II
Product Code: LPS, DFC
Dated: September 10, 1998
Received: September 11, 1998

Dear Dr. Leonardi:

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 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/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

510(k) Number (If Known): K980812

Device Name: IMx Homocysteine

Indications for Use:

The IMx Homocysteine assay is a Fluorescence Polarization Immunoassay (FPIA) for the quantitative measurement of total L-homocysteine in human serum or plasma on the IMx Analyzer.

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

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

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K980812