DEC 21 2001

Bayer Diagnostics
ACS:180 HCY Assay K013606

Section 2 – Summary of Safety and Effectiveness

1. Submitter Information

Contact Person:	Kenneth T. Edds, Ph.D.
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Date Summary Prepared:	10/24/01

2. Device Information

Propriety Name:	ACS:180 HCY Assay
Common Name:	HCY assay
Classification Name:	Homocysteine Assay
Class:	II
CFR:	862.1377
Product Code:	75 LPS

3. Predicate Device Information

Name:	IMx Homocysteine
Manufacturer:	
Manufactured by:	Axis-Shield ASA Ulvenveien 87 N-0581 Oslo, Norway
Manufactured for:	Abbott Laboratories Abbott Park Road Abbott Park, Il. 60064
510(k) Number:	K 992858

4. Device Description
The ACS:180 HCY assay is a competitive immunoassay using direct, chemiluminescent technology. It is intended to measure the amino acid Homocysteine (HCY) in serum or EDTA plasma. The homocysteine assay requires four separate reagents, which are added sequentially. A Reducing Reagent releases protein bound and dimerized HCY in a sample or control to free HCY. A Enzyme Reagent uses the enzyme S-adenosylhomocysteine hydrolase to convert the free HCY to S-adenosylhomocysteine (SAH). SAH from a calibrator, control, or sample competes with SAH bound to the Solid Phase for binding to a monoclonal anti SAH antibody-acridinium ester conjugate in the Lite Reagent. Following incubation, unbound SAH and anti SAH-acridinium ester conjugate are washed from the Solid Phase. The chemiluminescence of the acridinium ester bound to the Solid Phase is measured. The amount of chemiluminescence is inversely proportional to the amount of HCY that was present in the sample.

5. Statement of Intended Use
Intended for *in vitro* diagnostic use in the quantitative determination of total homocysteine (HCY) in serum or EDTA plasma using the ACS:180 System. This diagnostic test is designed to quantitatively measure HCY in serum or EDTA plasma. Such measurement can aid in the diagnosis and treatment of patients suspected of having homocysteinuria or hyperhomocysteinemia.

6. Summary of Technological Characteristics
The ACS:180 HCY assay is similar to the Abbott IMx Homocysteine assay in several ways. Both require a chemical and enzymatic step to occur before the actual immunoassay starts. The similarities between the Bayer and Abbott reagents are summarized below:

Step	Bayer Active Compound(s)	Abbott Active Compound(s)
Chemical reduction of protein bound HCY to free HCY	Dithiothreitol	Dithiothreitol
Enzymatic conversion of HCY to SAH	S-adenosyl homocysteine hydrolase	S-adenosyl homocysteine hydrolase
Analyte in Calibrator	SAH	SAH
Antibody	Mouse monoclonal anti-SAH	Mouse monoclonal anti-SAH

The systems differ in their detection systems, Abbott assay uses fluorescence polarization while the ACS:180 uses chemiluminescence.

7. Method Comparison
We have compared the ACS:180 HCY assay to the Abbott IMx Homocysteine assay in performance. 106 samples were assayed on both systems and yielded the following linear regression statistics:
IMx = 0.98 (ACS:180) + 0.43 μmol/L, R = 0.981

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 21 2001

Kenneth T. Edds, Ph.D.
Manager, Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, NY 10591-5097

Re: k013606
Trade/Device Name: Homocysteine Assay for the ACS:180
Regulation Number: 21 CFR 862.1377; 21 CFR 862.1150
Regulation Name: Urinary homocystine (non-quantitative) test system; Calibrator
Regulatory Class: Class II; Class II
Product Code: LPS; JIS
Dated: October 29, 2001
Received: October 31, 2001

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K013606

Device Name: HCY Assay for the ACS:180

Indications for Use:

Intended for *in vitro* diagnostic use in the quantitative determination of total homocysteine (HCY) in serum or EDTA plasma using the ACS:180® System. This diagnostic test is designed to quantitatively measure HCY in serum or EDTA plasma. Such measurement can aid in the diagnosis and treatment of patients suspected of having homocysteinuria or hyperhomocysteinemia.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013606

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-CounterUse_____

(Optional Format 1-2-96)