MAR 2 9 2006

510(k) Summary for N Latex HCY

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: k052788

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:

Distributor:

Dade Behring Marburg GmbH
Emil-von-Behring Str. 76
D-35001
Marburg, Germany

Contact Information:

Dade Behring Inc.
Glasgow Site
P.O. Box 6101
Newark, Delaware 19714
Attn: Kathleen Dray-Lyons
Tel: 781-826-4551
Fax: 781-826-2497

Preparation date: March 14, 2006

2. Device Name

N Latex HCY
N Protein Standard SL
N/T Protein Control SL/L, M and H

Classification: Class II; Class II; Class I
21 CFR 862.1377; 862.1150; 862.1660

Panel: Clinical Chemistry (75)

Product Code: LPS; JIT; JJX

3. Identification of the Legally Marketed Device:

Abbott IMx Homocysteine Assay – K992858

4. Device Description:

Bound homocysteine in the sample is reduced to free homocysteine by the action of dithiothreitol, and converted enzymatically to S-adenosyl-homocysteine (SAH) in the next step. Conjugated S-adenosyl-cysteine (SAC), added at the onset of the reaction, competes with the SAH in the sample for bonding by anti-SAH antibodies bound to polystyrene particles. In the presence of SAH, there is either no aggregation or a weaker aggregation of particles. In the absence of SAH in the sample, an aggregation of the polystyrene particles by the conjugated SAC occurs. The higher the SAH content of the reaction mixture is, the smaller the scattered light signal. The result is evaluated by comparison with a standard of known concentration.

5. Device Intended Use:

N Latex HCY:
In vitro diagnostic reagents for the quantitative determination of total homocysteine (HCY) in human serum, heparinized plasma and EDTA plasma by means of particle-enhanced immunonephelometry on the BN™ II and BN ProSpec® Systems. The device can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia and homocystinuria.

N Protein Standard SL:
Establishment of reference curves for the determination of IgG, IgG_{1-4}, IgA, IgM, IgE, C3c, C4, transferrin, albumin, α_1-antitrypsin, α_2-macroglobulin, haptoglobin, α_1-acid glycoprotein, prealbumin, hemopexin, ceruloplasmin, RbP, Ig/L-chain lambda & kappa, soluble transferrin receptor, ferritin, β_2-microglobulin, total protein and homocysteine by immunonephelometry with BN™ Systems.

N/T Protein Control SL/L, M and H:
N/T Protein Controls SL/L, M, and H are for use as accuracy and precision assayed controls in the determination of the following human serum proteins by immunonephelometry with BN™ Systems: IgG, IgG_{1-4}, IgA, IgM, C3c, C4, transferrin, albumin, α_1-antitrypsin, α_2-macroglobulin, haptoglobin, α_1-acid glycoprotein, prealbumin, hemopexin, ceruloplasmin, RbP, Ig/L-chain lambda & kappa, β_2-microglobulin, soluble transferrin receptor, ferritin, IgE, total protein and homocysteine.

6. Medical device to which equivalence is claimed and comparison information:

The N Latex HCY assay is substantially equivalent to the Abbott IMx Homocysteine assay
(K992858). The N Latex HCY assay, like the Abbott IMx Homocysteine assay is intended for use in the quantitative determination of total homocysteine (HCY) in human serum or plasma.

7. Device Performance Characteristics:

The N Latex HCY was compared to the Abbott IMx HCY assay by evaluating 73 plasma samples with concentrations ranging from 4.83 to 38.40 µmol/L. Regression analysis of the results yielded the following equation:

Method Comparison Study

N Latex HCY	(n=)	Slope	Intercept	Correlation Coefficient
	73	0.97	0.06	0.99

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 29 2006

Ms. Kathleen A. Dray-Lyons
Regulatory Affairs and Compliance Manager
Dade Behring, Inc.
Glasgow Bldg 500
P.O. Box 6101
Newark, DE 19714-6101

Re: k052788
Trade/Device Name: N Latex HCY
N Protein Standard SL
N/T Protein Control SL
Regulation Number: 21 CFR§862.1377
Regulation Name: Urinary homocystine (non-quantitative) test system
Regulatory Class: Class II
Product Code: LPS, JIX, JJY
Dated: February 17, 2006
Received: February 21, 2006

Dear Ms. Dray- Lyons:

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 (240) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications Statement

Device Name: **N Latex HCY**
N Protein Standard SL
N/T Protein Control SL

Indications for Use: K05 2788

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Prescription Use X
(Per 21 CFR 801 Subpart D)

Over-The-Counter-Use _____
(21 CFR 801)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K052788