MAR 2 8 2006

510(k) Summary for N Antisera to Human α_2-Macroglobulin

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: K053073

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

Manufacturer:	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:	October 28, 2005

2. **Device Name/ Classification:** N Antisera to Human α_2-Macroglobulin
Class: α_2-Macroglobulin Immunological Test System, Class II, 21 CFR 866.5620
Panel: Immunology
Product Code: DEB

3. **Identification of the Legally Marketed Device:**

N Antisera to Human α_2-Macroglobulin– K860894

4. **Device Description:**

Proteins contained in human body fluids form immune complexes in an immunochemical reaction with specific antibodies. These complexes scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the relevant protein in the sample. The result is evaluated by comparison with a standard of known concentration.

5. Device Intended Use:

In vitro diagnostic reagents for the quantitative determination of α_2-macroglobulin in human serum and heparinized plasma by means of immunonephelometry on the BN™ Systems.

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

The modified N Antisera to Human α_2-Macroglobulin assay is substantially equivalent to the N Antisera to Human α_2-Macroglobulin currently marketed (K860894). The modified N Antisera to Human α_2-Macroglobulin assay, like the current N Antisera to Human α_2-Macroglobulin assay, is intended for the quantitative determination of α_2-macroglobulin by means of immunonephelometry on the BN™ Systems.

7. Device Performance Characteristics:

To demonstrate equivalence in measurement between serum and heparinized plasma, a method comparison was performed. This study demonstrates equivalent performance with a correlation coefficient of 0.98

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Dade Behring, Inc.
c/o Ms. Kathleen A Dray-Lyons
Glasgow Site
P.O. Box 6101
Newark, DE 19714

Re: k053073
Trade/Device Name: N Antisera to Human α_2-Macroglobulin Assay
Regulation Number: 21 CFR 866.5620
Regulation Name: Alpha-2-Macroglobulin Immunological Test System
Regulatory Class: Class II
Product Code: DEB
Dated: October 28, 2005
Received: November 1, 2005

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 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 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance 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,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications Statement

K053073

Device Name: N Antisera to Human α_2-Macroglobulin Assay

Indications for Use:

In vitro diagnostic reagents for the quantitative determination of α_2-macroglobulin in human serum and heparinized plasma by means of immunonephelometery on the BN™ Systems. Measurement of α_2-macroglobulin may aid in the diagnosis of blood clotting or clot lysis disorders.

Prescription Use ✓
(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)

Maria Chan
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K053073