510(k) Summary
N Antisera to Human Complement Factors (C3c, C4)

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

Manufacturer:	Dade Behring Marburg GmbH Emil-von-Behring Str. 76 Marburg/Germany
Contact Information:	Dade Behring Inc. Glasgow Site P.O. Box 6101 Newark, Delaware 19714 Attn: Donna Wolf Tel: 302-631-0384
Preparation date:	March 14, 2005

2. **Device Name/ Classification:**
N Antisera to Human Complement Factors (C3c and C4) / Complement components C3, C4 immunological test system, Class II (866.5240)

3. **Identification of the Legally Marketed Device:**
N Antisera to Human Complement Factors (C3c and C4), K860894

4. **Device Description:**
Proteins contained in human body fluids form immune complexes in an immunochemical reaction with specific, purified rabbit antibodies to human C3 and C4.

5. **Device Intended Use:**
In vitro diagnostic reagents for the quantitative determination of complement factors (C3/C3c and C4/C4c) in human serum or heparinized or EDTA plasma by means of immunonephelometry on the BN* Systems as an aid in the diagnosis of immunologic disorders associated with complement C3 or C4 protein.

6. **Medical device to which equivalence is claimed and comparison information:**
The N Antisera to Human Complement Factors (C3c and C4) assay (modified) is substantially equivalent in intended use, principle and performance to the current N Antisera to Human Complement Factors (C3c and C4) assays. The modified assays, like the current assays are intended for use in the quantitative determination of complement factors (C3c and C4) in human serum. The modified assays differ from the currently marketed product in that the intended use has been expanded to include heparinized or EDTA plasma as specimen types.

7. **Device Performance Characteristics:**
Serum to Plasma Comparison:
To demonstrate equivalence in measurement between serum and heparinized or EDTA plasma, method comparisons were performed. The studies demonstrate equivalent performance with correlation coefficients between 0.98 and 0.99.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY - 2 2005

Dade Behring Inc.
c/o Ms. Donna A. Wolf
Regulatory Affairs and Compliance Manager
500 GBC Dr., MailStop 514
P.O. Box 6101
Newark, DE 19714

Re: k050665
Trade/Device Name: N Antisera to Human Complement Factors (C3c, C4)
Regulation Number: 21 CFR 866.5240
Regulation Name: Complement components immunological test system
Regulatory Class: Class II
Product Code: CZW, DBI
Dated: March 14, 2005
Received: March 15, 2005

Dear Ms. Wolf:

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.

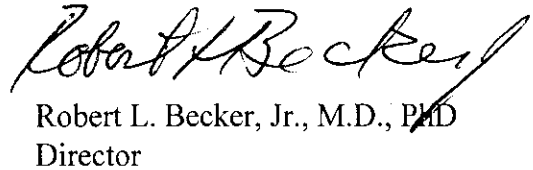
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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) 276-0131. 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/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

Indications for Use Statement

K050665

Device Name: N Antiserum to Human Complement Factors (C3c and C4)

Indications for Use:

In vitro diagnostic reagents for the quantitative determination of complement factors (C3/C3c and C4/C4c) in human serum or heparinized or EDTA plasma by means of immunonephelometry on the BN* Systems as an aid in the diagnosis of immunologic disorders associated with complement C3 or C4 protein.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K050665