



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

The N Antiserum to Human Albumin is substantially equivalent in intended use and results to the Beckman micro Albumin (MA) Reagent, in that both methods measure human albumin in urine.

**7. Proposed Device Performance Characteristics:**

**Correlation:**

Comparative studies to measure albumin in urine using N Antiserum to Human Albumin and Beckman micro Albumin (MA) Reagent were conducted. In 79 urine samples, ranging from 11.51 to 5259.42 mg/L, the correlation coefficient was 0.99, the y-intercept was -0.73 and the slope was 1.12.

**Precision:**

The N Antiserum to Human Albumin was evaluated for the precision of the assay in urine on the Behring Nephelometer. The data analysis protocol was adapted from NCCLS EP5-T. Intra-assay precision %CV ranged from 2.21 to 3.94, and inter-assay precision %CV ranged from 1.77 to 5.01.

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Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Ruth Forstadt  
Regulatory Affairs Associate  
Behring Diagnostics, Inc.  
151 University Avenue  
Westwood, Massachusetts 02090

OCT 20 1997

Re: K972929  
Trade Name: N Antiserum to Human Albumin  
Regulatory Class: II  
Product Code: DCF  
Dated: August 7, 1997  
Received: August 8, 1997

Dear Ms. Forstadt:

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 (Pre-market 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 requirement, 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 at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>"

Sincerely yours,



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): K972929

Device Name: \_\_\_\_\_

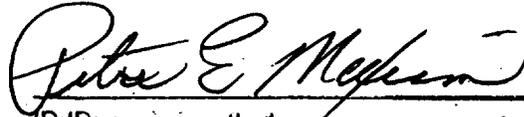
N Antiserum to Human Albumin

**Indications For Use:**

N Antiserum to Human Albumin is an *in vitro* diagnostic reagent intended to be used together with the Behring Nephelometer Systems in the measurement of albumin in human serum, cerebrospinal fluid and urine, used as an aid in the diagnosis of kidney and intestinal diseases.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



\_\_\_\_\_  
(Signature)  
D. Director, Office of Device Evaluation, CDRH, FDA  
5. Signature

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

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