

JUL 15 1999

K991705

**510(k) Summary  
For N Protein Standard UY**

**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: Rebecca S. Ayash  
Tel: 302-631-6276

Preparation date: May 19, 1999

**2. Device Name/ Classification:**

N Protein Standard UY: Calibrator

Classification Number: Class II (862.1150)

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

Protein Standard Urine Concentrate (K904254)

**4. Device Description:**

N Protein Standard UY (lyophilized) is a standard prepared from human urinary proteins with polygeline and preservative. It is intended to establish reference curves for the quantitative determination of  $\alpha_1$ -microglobulin by immunonephelometry with the Behring Nephelometer Systems (particle enhanced nephelometry).

**5. Device Intended Use:**

N Protein Standard UY is intended for preparing reference curves for the immunonephelometric determinations of  $\alpha_1$ -microglobulin in urine using the Behring Nephelometer Systems.

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

There are a number of *in vitro* diagnostic products that are used for the establishment of reference curves. One such product is the Protein Standard Urine Concentrate (K904254). The N Protein Standard UY is substantially equivalent in intended use to the Protein Standard Urine Concentrate. The N Protein Standard UY, like the Protein Standard Urine Concentrate is intended to be used for the calibration of an  $\alpha_1$ -microglobulin assay on the Behring Nephelometer Systems.

**7. Device Performance Characteristics:**

**Stability:**

Stability was evaluated according to in-house protocols and the standard was found to be stable for at least 12 months at +2° to +8° C, as originally packaged and for at least 14 days at +2° to +8° C, once opened.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

JUL 15 1999

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Rebecca S. Ayash  
Manager, Regulatory Affairs, Biology  
DADE BEHRING INC.  
Glasglow Site  
P.O. Box 6101  
Newark, Delaware 19714

Re: K991705  
Trade Name: N Protein Standard UY  
Regulatory Class: II  
Product Code: JIT  
Dated: May 19, 1999  
Received: May 19, 1999

Dear Ms. Ayash:

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 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). 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 (Premarket 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 requirements, 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.

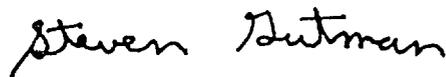
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style.

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

K991705

### Indications for Use Statement

**Device Name:** N Protein Standard UY

#### Indications for Use:

N Protein Standard UY is intended for preparing reference curves for the immunonephelometric determinations of  $\alpha_1$ -microglobulin in urine using the Behring Nephelometer Systems.

  
(Division Sign-Off)  
Division of Clinical Laboratory Services  
510(k) Number K991705

(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)

Prescription Use   
(Per 21 CFR 801.109)

Over-The-Counter-Use   
(Optional Format 1-2-96)

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