

**510(k) Summary  
For N Latex sTfR Reagent****1. Manufacture'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: Carolyn K. George  
Tel: 302-631-6283

Preparation date: April 5, 1999

**2. Device Name/ Classification:**

N Latex sTfR Reagent: Transferrin immunological test system

Classification Number: Class II (866.5880)

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

Quantikine IVD human sTfR assay

**4. Device Description:**

N Latex sTfR Reagent is intended to be used together with the Behring Nephelometer Systems for the quantitative determination of soluble transferrin receptor (sTfR) in human serum or heparinized human plasma.

**5. Device Intended Use:**

*In vitro* diagnostic reagent for quantitative determination of soluble transferrin receptor (sTfR) in human serum or heparinized plasma by particle enhanced nephelometry.

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

There are a number of *in vitro* diagnostic products in commercial distribution, which employ immunoassay techniques for the quantitative measurement of sTfR in human serum or plasma. One such product is the Quantikine IVD human sTfR immunoassay (K970718). N Latex sTfR is substantially equivalent in intended use and results obtained to the Quantikine IVD human sTfR immunoassay. The N Latex sTfR, like the Quantikine IVD human sTfR immunoassay is intended to be used for the quantitative determination of sTfR in human serum or plasma.

**7. Device Performance Characteristics:**

**Correlation:**

N Latex sTfR Reagent was compared to a commercially available sTfR assay by evaluation of 62 samples ranging from 0.41 to 3.5 mg/l. A correlation coefficient of 0.96 was obtained, with a y-intercept value of -0.19 and a slope of 0.81.

**Precision:**

Precision studies were performed by the evaluation of three levels of control material and two levels of human serum pools in a manner consistent with NCCLS Guideline EP5-T2. The inter-assay precision ranged from 0.8 to 1.2%, while the intra-assay precision ranged from 1.4 to 2.1%.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

AUG -2 1999

Ms. Rebecca S. Ayash  
Manager, Regulatory, Biology  
Dade Behring Inc.  
P.O. Box 6101  
Newark, Delaware 19714

Re: K991157  
Trade Name: N Latex sTfR Reagent  
Regulatory Class: II  
Product Code: DDG  
Dated: July 1, 1999  
Received: July 2, 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.

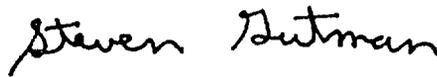
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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,



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

### Indications Statement

**Device Name:** N Latex sTfR Reagent

#### Indications for Use:

The N Latex sTfR Reagent is an *in vitro* diagnostic reagent for the quantitative determination of sTfR in human serum or heparinized plasma using the Behring Nephelometer Systems (BNA, BN100, & BNII), and aids in the diagnosis of malnutrition, acute inflammation, infection, and red blood cell disorders, such as iron deficiency anemia.



(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K 99 1157

(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)