NOV 23 1999

510(k) Summary for N Latex Ferritin

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: K993273

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: Rebecca S. Ayash Tel: 302-631-6276
Preparation date:	September 29, 1999

2. Device Name/ Classification:

N Latex Ferritin:	Ferritin immunological test system
Classification Number:	Class II (866.5340)

3. Identification of the Legally Marketed Device:

N Latex Ferritin (K950707)

4. Device Description:

Polystyrene latex particles coated with specific antibodies to human ferritin are agglutinated when mixed with samples containing ferritin. The intensity of scattered light in the nephelometer is proportional to the ferritin content of the sample; therefore, the ferritin concentration can be quantitated by comparison to dilutions of a standard of known concentration.

5. Device Intended Use:

In vitro diagnostic reagent for quantitative determination of ferritin in human serum or heparinized plasma by particle enhanced immunonephelometry 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 in commercial distribution, which employ immunoassay techniques for the quantitative determination of ferritin in human serum or plasma. One such product is the Dade Behring N Latex Ferritin assay (K950707). The proposed N Latex Ferritin is substantially equivalent in intended use and results obtained to the current N Latex Ferritin. The proposed N Latex Ferritin, like the current N Latex Ferritin is intended to be used for the quantitative determination of ferritin using the Behring Nephelometer Systems.

7. Device Performance Characteristics:

Correlation:

The proposed N Latex Ferritin assay was compared to the current N Latex Ferritin assay by evaluating 79 samples ranging from 12 to 440 µg/l. A correlation coefficient of 1.0 was obtained, with a y-intercept value of –0.87 and a slope of 1.05.

Precision:

Precision studies were performed by the evaluation of three levels of human serum pools. The precision data were generated in a manner consistent with NCCLS Guideline EP5-A. The inter-assay precision ranged from 1.2 to 3.1%, while the intra-assay precision ranged from 1.0 to 4.6%.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 23 1999

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

Re: K993273
Trade Name: N Latex Ferritin
Regulatory Class: II
Product Code: DBF
Dated: September 29, 1999
Received: September 30, 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.

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 Gutman

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

K993273

Device Name: N Latex Ferritin

Indications for Use:

N Latex Ferritin is an *in vitro* diagnostic reagent for the quantitative determination of ferritin in human serum or heparinized plasma by particle enhanced immunonephelometry using the Behring Nephelometer Systems, and aids in the diagnosis of diseases affecting iron metabolism, such as hemochromatosis (iron overload) and iron deficiency anemia.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter. Marker

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993273

Prescription Use ✓
(Per 21 CFR 801.109)

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