

JUL -7 1999

510(k) Summary For N Latex IgE mono Reagent

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: K 991787

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 24, 1999

2. Device Name/ Classification:

N Latex IgE mono Reagent: Immunoglobulins A, G, M, D, and E
immunological test system

Classification Number: Class II (866.5510)

3. Identification of the Legally Marketed Device:

N Latex IgE kit (K890530)

4. Device Description:

N Latex IgE mono Reagent is intended to be used together with the Behring Nephelometer Systems for the quantitative determination of Immunoglobulin E (IgE) in human serum or plasma.

5. Device Intended Use:

In vitro diagnostic reagent for quantitative determination of IgE in human serum or plasma by particle enhanced immunonephelometry using the Behring Nephelometer Systems.

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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 IgE in human serum or plasma. One such product is the Dade Behring N Latex IgE kit (K890530). N Latex IgE mono Reagent is substantially equivalent in intended use and results obtained to the N Latex IgE kit. The N Latex IgE mono Reagent, like the N Latex IgE kit is intended to be used for the quantitative determination of IgE in human serum or plasma using the Behring Nephelometer Systems.

7. Device Performance Characteristics:

Correlation:

The N Latex IgE mono assay was compared to the N Latex IgE assay by evaluating 70 samples ranging from 14 to 855 IU/ml. A correlation coefficient of 1.0 was obtained, with a y-intercept value of 6.1 and a slope of 1.0.

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 1.5 to 4.1%, while the intra-assay precision ranged from 1.7 to 3.0%.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K991787
Trade Name: N Latex IgE mono Reagent
Regulatory Class: II
Product Code: DGC
Dated: May 24, 1999
Received: May 25, 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.

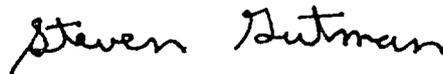
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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

K 991787

Device Name: N Latex IgE mono Reagent

Indications for Use:

In vitro diagnostic reagent for the quantitative determination of IgE in human serum or plasma by particle enhanced immunonephelometry using the Behring Nephelometer Systems, and aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number

K 991787

Prescription Use
(Per 21 CFR 801.109)

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