AUG - 7 2003

510(k) Summary for N Latex IgM

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: K032014

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: Kathleen Dray-Lyons Tel: 781-826-4551 Fax: 781-826-2497
Preparation date:	June 26, 2003

2. Device Name/ Classification:

N Latex IgM:	Immunoglobulin A, G, D and E immunological test system, Class II (866.5510)
Product Code:	81 CFN

3. Identification of the Legally Marketed Device:
Beckman Coulter IMMAGE® Immunochemistry System Low Concentration Immunoglobulin M (IGMLC) assay (K993547)

4. Device Description:
Polystyrene latex particles coated with antibodies specific to human IgM are agglutinated when mixed with samples containing human IgM. These aggregates scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the relevant protein in the sample. The result is evaluated by comparison with a standard of known concentration.

5. **Device Intended Use:**
In vitro diagnostic reagents for the quantitative determination of IgM in human cerebrospinal fluid (CSF) and in paired CSF/serum samples by means of particle-enhanced immunonephelometry using the BN™ Systems. The determination of IgM aids in the evaluation of the patient's immune system.

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 IgM in human serum or CSF. One such product is the Beckman Coulter IMMAGE® Immunochemistry System Low Concentration Immunoglobulin M (IGMLC) Assay (K993547). The N Latex IgM is substantially equivalent in intended use and results obtained to the IMMAGE® IGMLC assay.

7. **Device Performance Characteristics:**

Correlation:

Method Comparison Studies

Assay	Sample Type	(n=)	Slope	Intercept	Correlation Coefficient
N Latex IgM	CSF	24	1.04	-0.02	0.995
	Serum	50	0.91	+0.02	0.979
	CSF/Serum Ratio	24	1.03	-0.01	0.989

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG - 7 2003

Ms. Kathleen A. Dray-Lyons
Manager, Regulatory Affairs and Compliance
Dade Behring, Inc.
Glasgow Site
P.O. Box 6101
Newark, Delaware 19714

Re: k032014
Trade/Device Name: N Latex IgM
Regulation Number: 21 CFR § 866.5510
Regulation Name: Immunoglobulins A, G, M, D and E Immunological Test
Regulatory Class: II
Product Code: CFN
Dated: June 26, 2003
Received: June 30, 2003

Dear Ms. Dray-Lyons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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 Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications Statement

Device Name: N Latex IgM

Indications for Use:

N Latex IgM is an *in vitro* diagnostic test for the quantitative determination of IgM in human cerebrospinal fluid (CSF) and in paired CSF/serum samples by means of particle-enhanced immunonephelometry using the BN™ Systems. The determination of IgM aids in the evaluation of the patient's immune system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109)

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

J P Reeves for J. Bautista
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032014