510(k) Summary for
N Latex CDT

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: K060677

AUG 25 2006

1. **Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:**

Distributor:	Dade Behring Marburg GmbH Emil-von-Behring Str. 76 D-35001 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:	August 15, 2006

2. **Device Name** — N Latex CDT Kit

Classification: — Class I
21 CFR 862.1360

Panel: — Clinical Chemistry (75)

Product Code: — NAO

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

Axis-Shield %CDT Assay – K992502

4. Device Description:

The CDT in the sample competes with CDT-coated polystyrene particles for the bond to specific monoclonal antibodies against human CDT, which are likewise bound to polystyrene particles. In the presence of CDT in the sample, there is no or little aggregation of the polystyrene particles. In the absence of CDT in the sample, the polystyrene particles aggregate. The higher the CDT content in the assay, the lower the scattered light signal. The evaluation is performed by comparison with a standard of known concentration.

5. Device Intended Use:

In vitro diagnostic for the quantitative determination of carbohydrate-deficient transferrin (CDT) in human serum by means of particle-enhanced immunonephelometry using the BN™ II and BN ProSpec® System. The N Latex CDT assay must be run concurrently with the N Antisera to Human Transferrin assay so that the result can be expressed as a relative ratio, i.e., %CDT of the total transferrin. The calculation of %CDT can be used as a tool to identify possible chronic heavy alcohol consumption.

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

The N Latex CDT test kit is substantially equivalent to the Axis-Shield %CDT assay (K992502). The N Latex CDT assay, like the Axis-Shield %CDT assay, is an *in vitro* reagent system for the quantitative measurement of carbohydrate-deficient transferrin in human serum.

7. Device Performance Characteristics:

The N Latex CDT assay (y) was compared to a commercially available immunoassay (x) by evaluating 116 serum samples with %CDT concentrations ranging from 0.77 to 21.3 %CDT. Regression analysis of the results yielded the following equation:

$$y = 0.720x + 0.75 \text{ \%CDT}, \text{ correlation coefficient } 0.99$$

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

AUG 25 2006

Re: k060677
Trade/Device Name: N Latex CDT Kit
Regulation Number: 21 CFR 862.1360
Regulation Name: Gamma-glutamyl transpeptidase and isoenzymes test system
Regulatory Class: Class I
Product Code: NAO
Dated: July12, 2006
Received: July 13, 2006

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 (240) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications Statement

Device Name: **N Latex CDT Kit**

Indications for Use:

In vitro diagnostic for the quantitative determination of carbohydrate-deficient transferrin (CDT) in human serum by means of particle-enhanced immunonephelometry using the BN™ II and BN ProSpec® System. The N Latex CDT assay must be run concurrently with the N Antisera to Human Transferrin assay so that the result can be expressed as a relative ratio, i.e., %CDT of the total transferrin. The calculation of %CDT can be used as a tool to identify possible chronic heavy alcohol consumption.

Prescription Use ___X___
(Per 21 CFR 801 Subpart D)

Over-The-Counter-Use_____
(21 CFR 801)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K060677