JUL 27 2004

K041870

510(k) Summary
N Apolipoprotein Standard Serum

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

Manufacturer:	Contact Information:
Dade Behring Marburg GmbH Emil-von-Behring Str. 76 Marburg/Germany	Dade Behring Inc. Glasgow Site P.O. Box 6101 Newark, Delaware 19714 Attn: Donna Wolf Tel: 302-631-0384
Preparation date:	July 8, 2004

2. Device Name/ Classification:

N Apolipoprotein Standard Serum / Calibrator, Class II (862.1150)

3. Identification of the Legally Marketed Device:

Randox Apolipoprotein Calibrator (K023158)

4. Device Description:

N Apolipoprotein Standard Serum is a lyophilized calibrator prepared from human serum with stabilizers and preservative. It is intended to establish reference curves for the quantitative determination of Apolipoprotein A-I and Apolipoprotein B assays on BN™ Systems.

5. Device Intended Use:

For calibration of the Apolipoprotein A-I and Apolipoprotein B assays on BN™ Systems.

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

There are a number of in vitro diagnostic products that are used for the establishment of reference curves. One such product is the Randox Laboratories Apolipoprotein Calibrator (K023158). Both products are lyophilized human-based calibrators intended for the calibration of Apolipoprotein A-I and B.

7. Device Performance Characteristics:

Stability:
Stability was evaluated by testing N Apolipoprotein Standard Serum in duplicate at each time point for a total of three lots. The standard was evaluated at the recommended storage temperature of 2° to 8° C. Stability testing supports no significant change in recovery for at least 36 months, and for 15 days, once reconstituted.

The N Apolipoprotein Standard Serum is substantially equivalent to other comparable calibrator products in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 27 2004

Ms. Donna Wolf
Regulatory Affairs and Compliance Manger
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714

Re: k041870
Trade/Device Name: N Apolipoprotein Standard Serum
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: July 8, 2004
Received: July 13, 2004

Dear Ms. Wolf:

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,

Jean M. Cooper MS DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041870

Device Name: N Apolipoprotein Standard Serum

Indications For Use:

For calibration of the Apolipoprotein A-I and Apolipoprotein B assays on BN™ Systems.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041870