

SEP 28 2001

**510(k) Summary
For N Protein Standard SL**

K-012490

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: July 31, 2001

2. Device Name/ Classification:

N Protein Standard SL: Calibrator, Multi-Analyte

Classification Number: Class II (862.1150)

3. Identification of the Legally Marketed Device:

N Protein Standard SL (K002804)

4. Device Description:

N Protein Standard SL is a liquid standard prepared from human serum with stabilizers and preservative. It is intended to establish reference curves for the quantitative determination of human serum proteins by immunonephelometry with BN™ Systems (particle-enhanced nephelometry).

5. Device Intended Use:

Establishment of reference curves for the determination of IgG, IgG₁₋₄, IgA, IgM, IgE, C3c, C4, Transferrin, Albumin, α_1 -antitrypsin, α_2 -macroglobulin, Haptoglobin, α_1 -acid glycoprotein, Prealbumin, Hemopexin, Ceruloplasmin, RbP, Ig/L-chain lambda & kappa, soluble Transferrin Receptor (sTfR), Ferritin, β_2 -microglobulin, and Total protein by immunonephelometry with BN™ Systems.

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

The N Protein Standard SL (modified to include total protein) is substantially equivalent in intended use to the Dade Behring N Protein Standard SL (K002804) currently marketed. The modified N Protein Standard SL, like the current N Protein Standard SL is intended to be used for the calibration of human serum protein assays on BN™ Systems.

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7. Device Performance Characteristics:

Stability:

Stability was evaluated according to Dade Behring protocols and the standard was found to be stable for at least 24 months at +2° to +8° C, as originally packaged and for at least 14 days at +2° to +8° C, once opened.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 28 2001

Ms. Rebecca S. Ayash
Director, Regulatory Affairs
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714

Re: k012470
Trade/Device Name: N Protein Standard SL
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: July 31, 2001
Received: August 2, 2001

Dear Ms. Ayash:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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 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 for Use Statement

Device Name: N Protein Standard SL

Indications for Use:

Establishment of reference curves for the determination of IgG, IgG₁₋₄, IgA, IgM, IgE, C3c, C4, Transferrin, Albumin, α_1 -antitrypsin, α_2 -macroglobulin, Haptoglobin, α_1 -acid glycoprotein, Prealbumin, Hemopexin, Ceruloplasmin, RbP, Ig/L-chain lambda & kappa, soluble Transferrin Receptor (sTfR), Ferritin, β_2 -microglobulin, and Total protein by immunonephelometry with BN™ Systems.

(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)

Kenia Alexander for Juan Cooper
(Division Sign-Off)
Division of Clin: _____ ices
510(k) Number: K012470

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