

K964062

ATTACHMENT 2

NOV 21 1996

510(k) SUMMARY FOR N PROTEIN STANDARD SL

1. **Manufactures Name, Address, Telephone, and contact person, date of preparation:**

Manufacture	Behringwerke AG Postfach 1140 35001 Marburg Germany
Distributor	Behring Diagnostics Inc. 151 University Avenue Westwood, MA 02090 617-320-3000
Contact Person:	Laura LeBarron
Date of Preparation:	October 4, 1996

2. **Device Name/ Classification:**

N Protein Standard SL:	calibrator
Classification Number:	class II (862.1150)

3. **Identification of the legally marketed device:**

N Protein Standard SY

4. **Proposed Device Description:**

The proposed standard, N Protein Standard SL is a standard prepared from human serum (liquid) with stabilizers and preservative. It is intended to be used together with the Behring Nephelometer Systems (Behring Nephelometer K860894, Behring Nephelometer 100 K892223 and the Behring Nephelometer II K943997) to establish reference curves for the following tests:

IgG	Ceruloplasmin
IgA	RbP
IgM	Ig/L-chain, Kappa
C3c	Ig/L-chain, Lambda
C4	IgG 1
Transferin	IgG 2
Albumin	IgG 3

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$\alpha$ 1-antitrypsin ( $\alpha$ 1-proteinase inhibitor)	IgG 4
$\alpha$ 2-macroglobulin	$\beta$ 2-microglobulin
Haptoglobin	Ferritin
$\alpha$ 1-acid glycoprotein	IgE
Pre-albumin (transthyretin)	

**5. Proposed Device Intended Use:**

N Protein Standard SL is intended to be used for the establishment of reference curves.

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

N Protein Standard SL is substantially equivalent in intended use to the N Protein Standard SY. Both standards are *in vitro* diagnostic reagents intended for use as a multi-constituent standard for the establishment of reference curves. The N Protein Standard SL, like the N Protein Standard SY, is a multi-constituent standard in a blood based matrix. Also, both standards are used for the calibration of immunology assays.

The N Protein Standard SL differs from the N Protein Standard SY in that the N Protein Standard SY is a lyophilized standard while the N Protein Standard SL is a liquid standard.

**7. Proposed Device Performance Characteristics:**

**Precision and reproducibility:**

Precision studies using one lot of N Protein Standard SL were run on the Behring Nephelometer. The percent CVs ranged from 0.9 to 3.9 %.

**Stability**

Stability was run according to in-house protocols and the standard was found to be stable for at least 12 months at +2 to +8°C, as originally packaged and for at least 15 days at +2 to +8°C, once opened.