K962406

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Attachment 1

510(k) Summary of Safety and Effectiveness for N CRP Standard SY

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 Attn: Kathleen Dray-Lyons
Preparation date:	June 19, 1996

2. Device Name/ Classification:

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

3. Identification of the legally marketed device:

N Protein Standard SY

4. Proposed Device Description:

The proposed calibrator, N CRP Standard SY is a calibrator prepared from human serum (lyophilized) 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) for the calibration of the N Latex CRP mono test.

5. Proposed Device Intended Use:

N CRP Standard SY is intended to be used for the establishment of reference curves.

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

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

The N CRP Standard SY differs from the N Protein Standard SY in that the N Protein Standard SY is a multi-analyte calibrator while the N CRP Standard SY is a single analyte calibrator.

7. Proposed Device Performance Characteristics:

Precision and reproducibility:

Precision studies using one lot of N CRP Standard SY were run on the Behring Nephelometer. The %CVs ranged from 1.43 to 4.47%.

Stability

Stability was run according to in-house protocols and the control was found stable for at least 12 month lyophilized and 4 weeks once reconstituted.