

K960257

AUG -1 1996

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**510(k) Summary of Safety and Effectiveness for
N Antiserum to C1 Inhibitor**

1. Manufacturer Name, Address, phone number, contact name and date of preparation:

Manufacturer Behringwerke AG
 Postfach 1140
 35001 Marburg
 Germany

Distributor: Behring Diagnostics Inc.,
 151 University Avenue
 Westwood, MA 02090
 617-320-3023
 Contact name: Kathleen Dray-Lyons

date of preparation: June 27, 1996

2. Device Name/Classification:

Reagents for use in the determination of Complement C1 Inhibitor /Class II (866.5250)

3. Identification of the legally marketed device to which the submitter claims equivalence.

The Binding Site Limited BIND A RID™ C1

4. Proposed Device Description:

In vitro diagnostic reagent for the quantitative determination of C1 Inhibitor (C1-inactivator, C1-esterase inhibitor) in human plasma and serum with the Behring Nephelometers. Measurement of C1 inhibitor aids in the diagnosis of hereditary angioneurotic edema (increased blood vessel permeability causing swelling of tissues) and a rare form of angioedema associated with lymphoma (lymph node cancer).

In an immunochemical reaction, C1 Inhibitor in the human plasma sample form immune complexes with specific antibodies. These complexes scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the relevant protein in the sample. The result is evaluated by comparison with a standard of known concentration.

5. Proposed Device Intended Use:

In vitro diagnostic reagent for the quantitative determination of C1 Inhibitor (C1-inactivator, C1-esterase inhibitor) in human plasma and serum with the Behring Nephelometers. Measurement of C1 inhibitor aids in the diagnosis of hereditary angioneurotic edema

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(increased blood vessel permeability causing swelling of tissues) and a rare form of angioedema associated with lymphoma (lymph node cancer).

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

The C1 Inhibitor assay using the proposed product is substantially equivalent in intended use and results obtained to the BIND A RID™ C1 assay. The N Antiserum to C1 inhibitor like the proposed product, depends upon assaying standards of known C1 content to convert the measured value to concentration. Both tests utilize specific antibody to C1 inhibitor for capture of the C1 present in sample.

N Antiserum to C1 Inhibitor differs from the BIND A RID™ C1 test in that the BIND A RID™ C1 test measures the concentration of C1 Inhibitor in an unknown sample by measuring the ring diameter and manually reading off a calibration curve, while the N Antiserum to C1 Inhibitor measures C1 inhibitor concentration using a nephelometer. Also, the N Antiserum to C1 Inhibitor assay is based on a 5 point standard curve, whereas the BIND A RID™ C1 is based on a 3 point standard curve. Additionally, the BIND A RID™ C1 is intended for use with serum samples only, while the N Antiserum C1 is intended for use with both serum and plasma. These differences do not affect the safety and effectiveness as demonstrated by excellent correlation to the BIND A RID™ C1 test across the assay range.

7. Proposed Device Performance characteristics:

Correlation:

Results of comparative studies using the N Antiserum to C1 Inhibitor and the BIND A RID™ C1 for 50 serum samples gave a correlation coefficient of 0.973 and a y-intercept of 3.74 and a slope of 0.85.

Precision:

Inter-assay precision studies were run over a 5 day period, twice per day, to total n=10 precision ranged from 0.89-7.73 %CV. Intra-assay precision was calculated from n=30 precision ranges from 1.31 - 2.89 %CV.

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