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

The N/T Rheumatology Controls SL are substantially equivalent in intended use to the individual N/T CRP Control Serum, N/T RF Control Serum and N/T ASL Control Serum. All products are *in vitro* diagnostic reagents intended for use as a quality control material to monitor the accuracy of certain immunology procedures. The N/T Rheumatology Controls SL, however, eliminates using three separate controls since all three constituents are included in one vial.

The N/T Rheumatology Controls SL differ from the N/T CRP Control Serum, N/T RF Control Serum and N/T ASL Control Serum in that the N/T Rheumatology Controls SL are liquid while the individual controls are lyophilized and the N/T Rheumatology Controls SL are bi-level while the individual controls are single-level.

7. Proposed Device Performance Characteristics:

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Accuracy studies using multiple vials of the controls were run on three Behring Nephelometers. Two lots of each control were tested. Three lots of N Latex CRP mono reagent were assayed in replicates of five on the Behring Nephelometers. The mean values and the percent recovery from the assigned values were calculated for each parameter. The percent recoveries compared to assigned values ranged from 92.1 to 107.2%

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