

K 962694

JUL 22 1996

**510(k) Summary of Safety and Effectiveness for  
OPUS B12 Controls**

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

Manufacturer: Behring Diagnostics, Inc.  
151 University Avenue  
Westwood, MA 02090  
617-320-3117  
Contact name: Ruth C. Forstadt

Date of preparation: July 9, 1996

**2. Device Name/Classification:**

OPUS B12 Controls: Quality Control material (assayed)

Classification number: Class 1 (862.1660)

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

OPUS hCG Controls

**4. Proposed Device Description:**

The OPUS B12 Controls are liquid controls containing known levels of human Vitamin B12 (Cyanocobalamin) in processed Human Serum Albumin with sodium azide as a preservative. The control is provided at three levels (low, mid and high). The OPUS B12 Control is only for use with the OPUS B12 assay and has not been evaluated for use with other assays.

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**5. Proposed Device Intended Use:**

The OPUS B12 Controls are intended for use as quality control material to monitor the precision and accuracy of the OPUS B12 assay.

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

The OPUS B12 Controls are substantially equivalent in intended use to the OPUS hCG Controls. Both products are *in vitro* diagnostic reagents intended for use as a quality control material to monitor specific laboratory procedures. The OPUS B12 Controls like the OPUS hCG Controls are a tri-level serum-based matrix controls for specific OPUS assays. Both controls are provided with lot specific values and are for use with the OPUS assays only.

The OPUS B12 Controls differ from the OPUS hCG Controls in that the OPUS B12 Controls are for use with the OPUS B12 assay and contain known levels of Vitamin B12 while the OPUS hCG Controls are for use with the OPUS hCG assay and contain known levels of hCG.

**7. Proposed Device Performance Characteristics:**

Precision of the OPUS B12 Controls was evaluated on an OPUS Immunoassay System with the OPUS B12 assay. Intra assay precision was evaluated by running an n=18 with each level of the OPUS control. %CV's ranged from 4.2% to 9.4% for B12.

The inter assay precision was evaluated by running duplicate determinations for each level of control twice per day (AM and PM) for five days to total an n=20. %CV's ranged from 8.41% to 12.53% for B12.

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