

K961206

APR 23 1996

K-961206

**510(k) Summary of Safety and Effectiveness for
OPUS T3 Controls**

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

Manufacturer: Behring Diagnostics Inc.,
151 University Avenue
Westwood, MA 02090
617-320-3153
Contact name: Nancy M Johansen

date of preparation: March 26, 1996

2. Device Name/Classification:

Quality Control Material (assayed)/Class I (862.1660)

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

OPUS hCG Controls

2. Proposed Device Description:

The OPUS T3 Controls are liquid controls containing known levels of T3 in processed human serum with anti-microbial agents and sodium azide as preservatives. The control is provided at three levels (low, mid and high). The OPUS T3 control is only for use with the OPUS T3 assay and has not been evaluated for use with other assays.

3. Proposed Device Intended Use:

The OPUS T3 Controls are intended for use as quality control material to monitor the precision and accuracy of the OPUS T3 assay.

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

The OPUS T3 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 T3 Controls like the OPUS hCG Controls are liquid tri-level human serum based matrix controls. Both controls are provided with lot specific values and are for use with the OPUS assays only.

The OPUS T3 Controls differ from the OPUS hCG Controls in that the OPUS T3 Controls are for use with the OPUS T3 assay and contain known levels of T3 while the OPUS hCG Controls are for use with the OPUS hCG assay and contain known levels of hCG.

5. Proposed Device Performance Characteristics:

Precision of the OPUS T3 Controls was evaluated on an OPUS Immunoassay System. Intra assay precision was evaluated by running an n=20 with each level of the OPUS controls. %CV's ranged from 7.1 to 12.8 %.

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 13.1% to 17.9%.