

000 20 005

K 9543911

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

**1. Identification of the legally marketed device:**

Biorad Lymphochek® Immunoassay Plus<sup>TDM</sup> Control Levels 1,2 and 3

**2. Proposed Device Description:**

The OPUS® TDM Controls consist of three levels (low, intermediate, and high). The controls are prepared from pooled human serum with stabilizers and 0.075% sodium azide as a preservative. The OPUS® TDM Controls are intended for use with OPUS® assays only; these controls have not been evaluated for use with other immunoassay systems.

**3. Proposed Device Intended Use:**

OPUS® TDM Controls are intended for use as a quality control material to monitor the accuracy and precision of several OPUS® immunoassays for which there are 51 0(k)'s. OPUS TDM Control have been evaluated for use with the following OPUS® assays:

Carbamazepine	Digoxin	Gentamicin
Phenobarbital	Phenytoin	Theophylline
Tobramycin	Vancomycin	Valproic Acid

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

The 13 PUS® TDM Controls are substantially equivalent in intended use to the BIO-RAD Lyphochek® Immunoassay Plus<sup>TDM</sup> Control. Both manufacturer's controls are in vitro diagnostic reagents intended for use as a quality control material to monitor the precision and accuracy of certain immunoassay procedures. The OPUS® TOM Controls like the BIO-RAD controls are multi-analyte controls in a blood-based matrix.

The Behring OPUS® TDM Controls differ from the BIO-RAD Lyphochek® Immunoassay Plus<sup>TDM</sup> Control in that the OPUS® TDM Controls are intended for use with the OPUS® System only while the BIO-RAD controls can be used with multiple immunoassay systems.

**5. Proposed Device Performance Characteristics:**

**Precision and reproducibility:**

Precision was evaluated by running duplicate determinations for each level of control twice per day for five days. With-in run %CV's ranged from 1.10 to 11.2 and intra assay %CV's ranged from 1.9 to 12.3.