attachment 1 K960075

APR 25 1996

510(k) Summary of Safety and Effectiveness for OPUS CK-MB & Total CK 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: January 18, 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.

BIORAD Liquichek™ CK-MB Control Levels 1, 2 and 3

4. Proposed Device Description:

The OPUS CK-MB & Total CK Controls are bovine calf serum based controls consisting of three levels (low, mid and high) containing known levels of human CK-MB and rabbit skeletal CK

4. Proposed Device Intended Use:

The OPUS CK-MB & Total CK Controls are intended for use as quality control material to monitor the precision and accuracy of the OPUS CK-MB and Total CK assay.

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

The OPUS CK-MB & Total CK Controls are substantially equivalent in intended use to the BIORAD Liquichek™ CK-MB Controls. Both products are *in vitro* diagnostic reagents intended for use as a quality control material to monitor specific laboratory procedures. The OPUS CK-MB & Total CK Controls like the Liquichek™ CK-MB Controls are a tri-level serum-based matrix controls for specific cardiac assays. Both controls are provided with lot specific values. The OPUS CK-MB & Total CK Controls and the Liquichek™ CK-MB Controls both contain two analytes. Both the OPUS CK-MB & Total CK Controls and the Liquichek™ CK-MB Controls are provided with known values for Behring OPUS Immunoassay System.

The Behring Diagnostics' OPUS CK-MB & Total CK Controls differ from the BIORAD Liquichek™ CK-MB Controls in that the OPUS CK-MB & Total CK Controls can be stored at +2° to +8°C, while the BIORAD controls must be stored at -10° to -20°C. Also the OPUS CK-MB & Total CK Control is provided as lyophilized control while the Liquichek™ CK-MB Controls are provided in liquid form.

6. Proposed Device Performance Characteristics:

Precision of the OPUS CK-MB & Total CK Controls was evaluated on an OPUS Immunoassay System with the OPUS CK-MB and Total CK assays. Intra assay precision was evaluated by running an n=20 with each level of the OPUS controls. %CV's ranged from 7.5% to 10.7% for CK-MB and 6.8% to 7.1% for Total CK.

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 7.2% to 9.3% for CK-MB and 5.9% and 6.6% for Total CK.