K962841

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510(k) Summary of Safety and Effectiveness for OPUS Myoglobin 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 17, 1996

2. Device Name/Classification:

OPUS Myoglobin 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 Myoglobin Controls are lyophilized controls containing known levels of human myoglobin in processed human serum. The control is provided at three levels (low, mid and high). The OPUS Myoglobin Control is only for use with the OPUS Myoglobin assay and has not been evaluated for use with other assays.

5. Proposed Device Intended Use:

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

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

The OPUS Myoglobin 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 Myoglobin Controls, like the OPUS hCG Controls, are a tri-level serum-based matrix control for specific OPUS assays. Both controls are provided with lot specific values and are for use with the OPUS assays only.

The OPUS Myoglobin Controls differ from the OPUS hCG Controls in that the OPUS Myoglobin Controls are for use with the OPUS Myoglobin assay and contain known levels of myoglobin, while the OPUS hCG Controls are for use with the the OPUS hCG assay and contain known levels of hCG. Also, the OPUS Myoglobin control is provided as a lyophilized control while the OPUS hCG controls are provided in a liquid form.

7. Proposed Device Performance Characteristics:

Precision of the OPUS Myoglobin Controls was evaluated on an OPUS Immunoassay System with the OPUS Myoglobin assay. Intra assay precision was evaluated by running an n=20 with each level of the OPUS control. %CV's ranged from 4.27% to 6.05% for myoglobin.

The inter assay precision was evaluated by running duplicate determinations for each level of control twice over a 15 day period to total an n=8. %CV's ranged from 6.55% to 10.54% for myoglobin.